



SAFETY DATA SHEET

Revision date 25-Feb-2025

Version 1

Page 1 / 11

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

1.1. Product identifier

Product Name PF-07817883 MCC Co-Processed
Product Code(s) PF01337
Trade Name: Not applicable
Chemical Family: Not determined

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

Recommended Use Pharmaceutically active formulation

1.3. Details of the supplier of the safety data sheet

Pfizer Research and Development
445 Eastern Point Road
Groton, CT USA
1-800-879-3477

Pfizer Ireland Pharmaceuticals
OSG Building
Ringaskiddy, Co. Cork.
Ireland
+353 21 4378701

E-mail address pfizer-MSDS@pfizer.com

1.4. Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

GHS - Classification: This substance is classified as not hazardous according to regulation (EC) 1272/2008 [CLP].

OSHA Classification

Physical Hazard Combustible Dust

2.2. Label elements

Signal word Warning
Hazard statements OSHA - May form combustible dust concentrations in air

Supplemental Hazard Compound, not fully tested, hazards unknown.

2.3. Other hazards

Other hazards An Occupational Exposure Value has been established for this substance (see Section 8).

SAFETY DATA SHEET

Product Name PF-07817883 MCC Co-Processed
Revision date 25-Feb-2025

Page 2 / 11
Version 1

PBT & vPvB

Endocrine Disruptor Information

The product does not contain any substance(s) classified as PBT or vPvB.

This product does not contain any known or suspected endocrine disruptors.

Note:

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

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Substances

Not applicable

3.2 Mixtures

NonHazardous

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
PF-07817883 (CAS #: PROPRIETARY)	85 - 90	-	Not Listed	Not classified	Not classified	No data available	No data available
Microcrystalline cellulose (CAS #: 9004-34-6)	5 - 10	-	232-674-9	Not classified	Not classified	No data available	No data available

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

Acute Toxicity Estimate

Chemical name	Oral LD50 mg/kg	Dermal LD50 mg/kg	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Microcrystalline cellulose 9004-34-6	5000	2000	5.8	No data available	No data available

Additional information

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation

Remove to fresh air. Seek immediate medical attention/advice.

Eye contact

Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.

SAFETY DATA SHEET

Product Name PF-07817883 MCC Co-Processed
Revision date 25-Feb-2025

Page 3 / 11
Version 1

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.

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

Most important symptoms and effects For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

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

Note to physicians None.

Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media Dry chemical, CO2, alcohol-resistant foam or water spray.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical Dusts or fumes may form explosive mixtures in air. Fine particles (such as dust and mists) may fuel fires/explosions.

Hazardous combustion products Carbon monoxide, carbon dioxide, nitrogen oxides and fluorine-containing compounds

Explosion data

Sensitivity to mechanical impact No information available.

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

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

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

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 Contain the source of the spill or leak. Collect spilled material by a method that controls dust generation. Avoid use of a filtered vacuum to clean spills of dry solids. Clean contaminated surface thoroughly.

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

SAFETY DATA SHEET

Product Name PF-07817883 MCC Co-Processed
Revision date 25-Feb-2025

Page 4 / 11
Version 1

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

Ground and bond all bulk transfer equipment. Avoid open handling. Minimize dust generation. Use local exhaust ventilation or perform work under fume hood/fume cupboard. Avoid inhalation and contact with skin, eye, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. 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.

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions

Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

7.3. Specific end use(s)

Specific use(s)

Pharmaceutically active formulation.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure Limits

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

Microcrystalline cellulose

ACGIH TLV	10 mg/m ³
Denmark	1 mg/m ³
Estonia	10 mg/m ³
	2 mg/m ³
Finland	2 mg/m ³
France	10 mg/m ³
	1 mg/m ³
Hungary	2 mg/m ³
Ireland	10 mg/m ³
	STEL: 30 mg/m ³
Latvia	2 mg/m ³
	6 mg/m ³
Poland	2.0 mg/m ³
Romania	10 mg/m ³
Russia	TWA: 6 mg/m ³
	MAC: 10 mg/m ³
Spain	10 mg/m ³
Switzerland	3 mg/m ³
	2 mg/m ³
OSHA PEL	15 mg/m ³

SAFETY DATA SHEET

Product Name PF-07817883 MCC Co-Processed
Revision date 25-Feb-2025

Page 5 / 11
Version 1

United Kingdom

5 mg/m³
(vacated) TWA: 15 mg/m³ total dust
(vacated) TWA: 5 mg/m³ respirable fraction
(vacated) TWA: 5 mg/m³
(vacated) STEL: 10 mg/m³
TWA: 10 mg/m³
TWA: 4 mg/m³
STEL: 20 mg/m³
STEL: 12 mg/m³

Pfizer Occupational Exposure Band (OEB) Statement:

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

PF-07817883

Pfizer Occupational Exposure Band (OEB):

OEB 3 - Contact Hazards Unknown (control exposure to the range of 10ug/m³ to < 100ug/m³)

8.2. Exposure controls

Engineering controls

Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels to below the OEB range.

Personal protective equipment

Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes. Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Eye/face protection

Wear safety goggles as minimum protection. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

Hand protection

Wear 2 layers of impervious disposable gloves (e.g. Nitrile, etc.) to prevent skin contact. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).

Skin and body protection

Wear impervious protective clothing to prevent skin contact – consider use of disposable clothing where appropriate. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).

Respiratory protection

Under normal conditions of use, if the applicable Occupational Exposure Band (OEB) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEB (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.).

Thermal hazards

No information available.

SAFETY DATA SHEET

Product Name PF-07817883 MCC Co-Processed
Revision date 25-Feb-2025

Page 6 / 11
Version 1

Environmental exposure controls No information available.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state	Solid
Color	White
Odor	No information available.
Odor threshold	No information available

<u>Property</u>	<u>Values</u>
Melting point / freezing point	No data available
Boiling point or initial boiling point and boiling range	No data available
Flammability (solid, gas)	No data available
Lower and upper explosion limit/flammability limit	
Lower explosion limit	No data available
Upper explosion limit	No data available
Flash point	No data available
Autoignition temperature	No data available
Decomposition temperature	
SADT (°C)	No data available
pH	No data available
pH (as aqueous solution)	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Solubility	No data available
Vapor pressure	No data available
Density and/or relative density	No data available
Bulk density	No data available
Liquid Density	No data available
Vapor density	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available

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

PF-07817883

Predicted 7.4 Log D 0.338

9.2. Other information

Molecular formula	Mixture
Molecular weight	Mixture
pKa:	

9.2.1. Information with regard to physical hazard classes

No information available

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

SAFETY DATA SHEET

Product Name PF-07817883 MCC Co-Processed
Revision date 25-Feb-2025

Page 7 / 11
Version 1

Stability Stable under normal conditions.

Explosion data

Sensitivity to mechanical impact No information available.

Sensitivity to static discharge No information available.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

10.4. Conditions to avoid

Conditions to avoid

Fine particles (such as dust and mists) may fuel fires/explosions.

10.5. Incompatible materials

Incompatible materials

As a precautionary measure, keep away from strong oxidizers.

10.6. Hazardous decomposition products

Hazardous decomposition products No data available.

Section 11: TOXICOLOGICAL INFORMATION

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

General Information:

Toxicological properties have not been thoroughly investigated. The information in this section describes the 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: headache.

Acute toxicity

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

Serious eye damage/eye irritation

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

Skin corrosion/irritation

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

Respiratory or skin sensitization

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

STOT - single exposure

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

STOT - repeated exposure

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

Reproductive toxicity

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

Germ cell mutagenicity

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

Carcinogenicity

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

Aspiration hazard

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

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

PF-07817883

Rat Oral NOAEL 1000 mg/kg

Microcrystalline cellulose

Rat Oral LD50 > 5000 mg/kg

Rabbit Dermal LD50 > 2000 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Microcrystalline cellulose	> 5 g/kg (Rat)	> 2000 mg/kg (Rabbit)	> 5800 mg/m ³ (Rat) 4 h

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

Microcrystalline cellulose

Skin irritation Rabbit Non-irritating

Eye irritation Rabbit Non-irritating

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

PF-07817883 SDD(75)

2 Week(s) Rat Oral 1000 mg/kg/day NOAEL None identified

2 Week(s) Monkey Oral 1000 mg/kg/day NOAEL None identified

SAFETY DATA SHEET

Product Name PF-07817883 MCC Co-Processed
Revision date 25-Feb-2025

Page 8 / 11
Version 1

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

PF-07817883 SDD(75)

Embryo / Fetal Development Rat Oral 1000 mg/kg/day NOAEL Maternal toxicity, Developmental toxicity
Embryo / Fetal Development Rabbit Oral 300 mg/kg/day NOAEL Maternal Toxicity, Developmental toxicity
Reproductive & Fertility Rat Oral 1000 mg/kg/day NOAEL Maternal Toxicity, Paternal toxicity, Fertility

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

PF-07817883

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

In Vitro Micronucleus Human Lymphocytes Negative

PF-07817883 SDD(75)

In Vivo Micronucleus Rat Bone Marrow Negative

Carcinogenicity

Not listed as a carcinogen by IARC, NTP or US OSHA.

Microcrystalline cellulose

NTP

Known Human Carcinogen

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties Based on available data, the classification criteria are not met.

11.2.2. Other information

Other adverse effects

No information available.

Section 12: ECOLOGICAL INFORMATION

Environmental Overview:

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

12.1. Toxicity

No information available

12.2. Persistence and degradability

Persistence and degradability

No information available.

12.3. Bioaccumulative potential

Bioaccumulation

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

PF-07817883

Predicted 7.4 Log D 0.338

12.4. Mobility in soil

Mobility in soil

No information available.

12.5. Results of PBT and vPvB assessment

SAFETY DATA SHEET

Product Name PF-07817883 MCC Co-Processed
Revision date 25-Feb-2025

Page 9 / 11
Version 1

PBT and vPvB assessment No information available.

12.6. Endocrine disrupting properties

Endocrine disrupting properties Based on available data, the classification criteria are not met.

12.7. Other adverse effects

Other adverse effects No information available.

PMT or vPvM properties Based on available data, the classification criteria are not met.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste from residues/unused products

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 wastewater 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.

Section 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.

UN number:	Not applicable
UN proper shipping name:	Not applicable
Transport hazard class(es):	Not applicable
Packing group:	Not applicable
Environmental Hazard(s):	Not applicable

Section 15: REGULATORY INFORMATION

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

PF-07817883

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
EINECS	Not Listed

Microcrystalline cellulose

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	carcinogen 12/18/2009
TSCA	Present
EINECS	232-674-9

SAFETY DATA SHEET

Product Name PF-07817883 MCC Co-Processed
Revision date 25-Feb-2025

Page 10 / 11
Version 1

AICS

Present

National regulations

France

Occupational Illnesses (R-463-3, France)

Chemical name	French RG number
Microcrystalline cellulose 9004-34-6	RG 66

Germany

Chemical Prohibition Ordinance (ChemVerbotsV)

Not applicable

TRGS 905

Not applicable

Switzerland

Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC) SR 814.018 Not applicable

Storage of Hazardous Material Not applicable

WPO (GSchV) SR 814.201; WPA (GSchG) SR 814.20 Not applicable

Major Accidents Ordinance SR 814.012 Not applicable

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 (EU) 2024/590

Not applicable.

Explosives Precursors Marketing and Use (2019/1148)

Not applicable

Legend:

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

DSL/NDL - 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 Chemicals Inventory

PICCS - Philippines Inventory of Chemicals and Chemical Substances

AICS - Australian Inventory of Chemical Substances

NZIoC - New Zealand Inventory of Chemicals

TCSI - Taiwan Chemical Substance Inventory

SAFETY DATA SHEET

Product Name PF-07817883 MCC Co-Processed
Revision date 25-Feb-2025

Page 11 / 11
Version 1

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

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.

Reason for revision New data sheet.

Revision date 25-Feb-2025

Prepared By Pfizer Global Environment, Health, and Safety

Pfizer Inc believes that the information contained in this 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.