

# MYCOPHENOLATE MOFETIL CRS

## Safety Data Sheet

Safety Data Sheet in accordance with Regulation (EC) No. 1907/2006, as amended.

Date of issue: 27/06/2013

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Version: 6.0

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

#### 1.1. Product identifier

Product form : Substance  
Trade name : MYCOPHENOLATE MOFETIL CRS  
CAS No : 128794-94-5  
Product code : Y0000489  
Other means of identification : RTECS No : MP7746700

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

##### 1.2.1. Relevant identified uses

Main use category : The product is intended for research, analysis and scientific education.  
Use of the substance/mixture : For professional use only  
Function or use category : Laboratory chemicals

##### 1.2.2. Uses advised against

No additional information available

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

European Directorate for the Quality of Medicines & Healthcare  
EDQM, Council of Europe  
F-67081 Strasbourg  
T +33(0)388412035 - F +33(0)388412771

#### 1.4. Emergency telephone number

Emergency number : +44(0)1235239670

### SECTION 2: Hazards identification

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

##### Classification according to Regulation (EC) No. 1272/2008 [CLP]

Repr. 1B H360D  
Acute Tox. 4 (Oral) H302  
Aquatic Acute 1 H400  
Aquatic Chronic 1 H410

Full text of H-phrases: see section 16

##### Classification according to Directive 67/548/EEC or 1999/45/EC

Repr.Cat.2; R61  
Xn; R22  
N; R50/53  
Full text of R-phrases: see section 16

##### Adverse physicochemical, human health and environmental effects

No additional information available

# MYCOPHENOLATE MOFETIL CRS

## Safety Data Sheet

Safety Data Sheet in accordance with Regulation (EC) No. 1907/2006, as amended.

### 2.2. Label elements

#### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :



Signal word (CLP) :

Danger

Hazard statements (CLP) :

H302 - Harmful if swallowed  
H360D - May damage the unborn child  
H410 - Very toxic to aquatic life with long lasting effects

Precautionary statements (CLP) :

P201 - Obtain special instructions before use  
P202 - Do not handle until all safety precautions have been read and understood  
P264 - Wash hands and other exposed areas thoroughly after handling  
P273 - Avoid release to the environment  
P281 - Use personal protective equipment as required  
P301+P312 - IF SWALLOWED: call a POISON CENTER or doctor/physician if you feel unwell  
P308+P313 - IF exposed or concerned: Get medical advice/attention  
P330 - Rinse mouth  
P391 - Collect spillage  
P501 - Dispose of contents/container to : Hazardous waste. Comply with applicable regulations

### 2.3. Other hazards

Other hazards not contributing to the classification

: Exposure may produce an allergic reaction.

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Name	Product identifier	%	Classification according to Directive 67/548/EEC
MYCOPHENOLATE MOFETIL (Main constituent)	(CAS No)128794-94-5	≤ 100	Repr.Cat.2; R61 Xn; R22 N; R50/53

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
MYCOPHENOLATE MOFETIL (Main constituent)	(CAS No)128794-94-5	≤ 100	Repr. 1B, H360D Acute Tox. 4 (Oral), H302 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

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

### 3.2. Mixture

Not applicable

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

First-aid measures general : If you feel unwell, seek medical advice (show the label where possible). Delayed adverse effects possible. Active component. Pharmaceuticals. For further information refer to Summary of Product Characteristics.

First-aid measures after inhalation : Move to fresh air in case of accidental inhalation. Assure fresh air breathing. Obtain medical attention if breathing difficulty persists.

First-aid measures after skin contact : Rinse skin with water/shower. Wash with plenty of soap and water.

First-aid measures after eye contact : Rinse with water while holding the eyes wide open. Contact lenses should be removed. Obtain medical attention if pain, blinking or redness persist.

First-aid measures after ingestion : Rinse mouth out with water. The following symptoms may occur: (see section(s) : 2, 4.2). If you feel unwell, seek medical advice. Prolonged medical observation may be indicated. (see section(s) : 4.3). The affected person must rest and be kept under medical observation.

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

Symptoms/injuries : See Heading 2. Immune system disorders. Blood and lymphatic system disorders. Neoplasms benign, malignant and unspecified (incl cysts and polyps). nausea, vomiting.

# MYCOPHENOLATE MOFETIL CRS

## Safety Data Sheet

Safety Data Sheet in accordance with Regulation (EC) No. 1907/2006, as amended.

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

In all cases of doubt, or when symptoms persist, seek medical attention. If possible show this sheet, if not available show packaging or label. If the occupational exposure limit is exceeded : Specific medical surveillance.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable extinguishing media : Small amounts: Use extinguishing media appropriate for surrounding fire. Extinguishing blanket. Carbon dioxide. Dry powder. Large amounts: Not applicable.  
Unsuitable extinguishing media : Water may be ineffective in firefighting due to low solubility.

### 5.2. Special hazards arising from the substance or mixture

No additional information available

### 5.3. Advice for firefighters

Precautionary measures fire : Small amounts: Use normal individual fire protective equipment. Large amounts: Not applicable.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

General measures : Avoid raising dust. Wear suitable protective clothing, gloves and eye or face protection. Avoid any direct contact with the product. Evacuate unnecessary personnel. Large amounts: Not applicable.

#### 6.1.1. For non-emergency personnel

Protective equipment : See Headings 7 and 8.  
Emergency procedures : Spill should be handled by trained cleaning personnel properly equipped with respiratory and eye protection. Wear suitable protective clothing and gloves.

#### 6.1.2. For emergency responders

No additional information available

### 6.2. Environmental precautions

No additional information available

### 6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Sweep spilled substance into containers; if appropriate, moisten first to prevent dusting. Ensure waste is collected and contained. Clean thoroughly. Poorly soluble in water. Clean with the help of detergents. Collect all waste in suitable and labelled containers and dispose according to local legislation. Wash the non-recoverable remainder with : Sodium hypochlorite solution.

### 6.4. Reference to other sections

(see section(s) : 8, 13).

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Additional hazards when processed : Small amounts: See Heading 1. When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us. The attention of the user is drawn to the risks possibly incurred by using the product for any other purpose than that for which it was intended. Avoid contact during pregnancy/while nursing.  
Precautions for safe handling : Handle and open container with care. See Heading 8. Do not handle until all safety precautions have been read and understood. Avoid any direct contact with the product. Obtain special instructions before use.  
Hygiene measures : Handle in accordance with good industrial hygiene and safety procedures. Small amounts: Material should be handled in a laboratory hood whenever possible.

### 7.2. Conditions for safe storage, including any incompatibilities

Technical measures : Comply with applicable regulations.  
Storage conditions : To guarantee the quality and properties of the product, keep : dry, Keep in a cool, well-ventilated place away from heat. Store in original container. Store according to local legislation.  
Incompatible products : Strong oxidizing agents.

### 7.3. Specific end use(s)

See Heading 1.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

No additional information available

# MYCOPHENOLATE MOFETIL CRS

## Safety Data Sheet

Safety Data Sheet in accordance with Regulation (EC) No. 1907/2006, as amended.

### 8.2. Exposure controls

Appropriate engineering controls : Material should be handled in a laboratory hood whenever possible.  
Personal protective equipment : Gloves. Safety glasses. Protective clothing. Dust production: dust mask with filter type P3.



Hand protection : Gloves. Chemical resistant PVC gloves (to European standard EN 374 or equivalent).  
Eye protection : Wear eye protection. DIN EN 166.  
Skin and body protection : Lab coat. Wear suitable protective clothing. DIN EN 13034.  
Respiratory protection : Quarter mask (DIN EN 140). Wear appropriate breathing apparatus if air renewal not sufficient to maintain dust/vapour under TLV.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state : Solid  
Appearance : Crystalline powder. white. Powder.  
Colour : No data available  
Odour : Not applicable. See Heading 2, 4.2, 8.  
Odour threshold : No data available  
pH : No data available  
Relative evaporation rate (butylacetate=1) : No data available  
Melting point : 96 °C  
Freezing point : No data available  
Boiling point : No data available  
Flash point : No data available  
Self ignition temperature : No data available  
Decomposition temperature : No data available  
Flammability (solid, gas) : No data available  
Vapour pressure : No data available  
Relative vapour density at 20 °C : No data available  
Relative density : No data available  
Solubility : Acetone.  
Water: < 1 mg/l  
Log Pow : 1,45 at 20°C (pH 7.4)  
Log Kow : No data available  
Viscosity, kinematic : No data available  
Viscosity, dynamic : No data available  
Explosive properties : No data available  
Oxidising properties : No data available  
Explosive limits : No data available

### 9.2. Other information

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

Stable under normal conditions.

### 10.2. Chemical stability

No additional information available

### 10.3. Possibility of hazardous reactions

Small amounts: When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us. Large amounts: Not applicable.

### 10.4. Conditions to avoid

No additional information available

### 10.5. Incompatible materials

Small amounts: None under normal use. Large amounts: Not applicable.

# MYCOPHENOLATE MOFETIL CRS

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### 10.6. Hazardous decomposition products

When heated to decomposition, emits dangerous fumes. Large amounts: Not applicable.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity : Harmful if swallowed.

MYCOPHENOLATE MOFETIL CRS(128794-94-5)	
LD50 oral rat	250 - 500 mg/kg
ATE (oral)	500,000 mg/kg

Skin corrosion/irritation : Not classified

Serious eye damage/irritation : Not classified

Respiratory or skin sensitisation : Not classified

Germ cell mutagenicity : Not classified

Carcinogenicity : Not classified

Reproductive toxicity : May damage the unborn child.

Specific target organ toxicity (single exposure) : Not classified

Specific target organ toxicity (repeated exposure) : Not classified

Aspiration hazard : Not classified

Potential Adverse human health effects and symptoms : Avoid any direct contact with the product. Small amounts: When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us. See first aid section of this material safety data sheet. Large amounts: Not applicable.

## SECTION 12: Ecological information

### 12.1. Toxicity

Ecology - general : Small amounts: See Heading 2. Poorly soluble in water. No data available on ecotoxicity. Hazardous waste. Use suitable disposal containers. Large amounts: Not applicable.

MYCOPHENOLATE MOFETIL CRS(128794-94-5)	
EC50 Daphnia 1	> 100 mg/l EC50 - 48 Hour - Daphnia magna

### 12.2. Persistence and degradability

MYCOPHENOLATE MOFETIL CRS(128794-94-5)	
Biodegradation	< 6

### 12.3. Bioaccumulative potential

MYCOPHENOLATE MOFETIL CRS(128794-94-5)	
Log Pow	1,45 at 20°C (pH 7.4)

### 12.4. Mobility in soil

No additional information available

### 12.5. Results of PBT and vPvB assessment

No additional information available

### 12.6. Other adverse effects

No additional information available

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Regional legislation (waste) : Dispose in a safe manner in accordance with local/national regulations.

Waste disposal recommendations : Do not empty into drains, dispose of this material and its container at hazardous or special waste collection point.

## SECTION 14: Transport information

In accordance with ADR / RID / ADNR / IMDG / ICAO / IATA

### 14.1. UN number

UN-No : 2811

UN-No.(IATA) : 2811

UN-No. (IMDG) : 2811

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### 14.2. UN proper shipping name

Proper Shipping Name : TOXIC SOLID, ORGANIC, N.O.S.  
Transport document description : UN 2811 TOXIC SOLID, ORGANIC, N.O.S., 6.1, III, (E)

### 14.3. Transport hazard class(es)

Class (UN) : 6.1  
Class (IATA) : 6.1  
Class (IMDG) : 6.1

### 14.4. Packing group

Packing group (UN) : III  
Packing group (IMDG) : III

### 14.5. Environmental hazards

Dangerous for the environment :

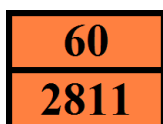


Other information : No supplementary information available.

### 14.6. Special precautions for user

#### 14.6.1. Overland transport

Hazard identification number (Kemler No.) : 60  
Classification code (UN) : T2  
Orange plates :



Tunnel restriction code : E  
LQ : LQ09  
Excepted quantities (ADR) : E1

#### 14.6.2. Transport by sea

Ship Safety Act : Toxic and infectious substances/Toxic substances  
Port Regulation Law : Toxic and infectious substances/Toxic substances  
MFAG-No : 154

#### 14.6.3. Air transport

Civil Aeronautics Law : Toxic and infectious substances/Toxic substances

### 14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

## SECTION 15: Regulatory information

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

#### 15.1.1. EU-Regulations

No REACH Annex XVII restrictions

#### 15.1.2. National regulations

No additional information available

### 15.2. Chemical safety assessment

No additional information available

## SECTION 16: Other information

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Full text of R-, H- and EUH-phrases::

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Acute 1	Hazardous to the aquatic environment — AcuteHazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1
Repr. 1B	Reproductive toxicity, Category 1B
H302	Harmful if swallowed
H360D	May damage the unborn child
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects
R22	Harmful if swallowed
R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
R61	May cause harm to the unborn child
N	Dangerous for the environment
Xn	Harmful

SDS EU (REACH Annex II)

*This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product*