

# 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 23-Mar-2023

Revision Number 1

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

- 1.1. Product identifier
- Product Code(s) CAT 1254
- **Product Name** Mycophenolate Mofetil

Form 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)	627-027-6
CAS No	128794-94-5
Chemical name	Mycophenolate Mofetil
Pure substance/mixture	Substance
Formula	C23H31NO7
Molecular weight	433.49

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

**Recommended use** Laboratory use

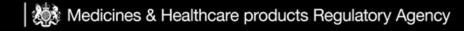
Uses advised against No information available

### 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





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### CAT 1254 - Mycophenolate Mofetil

For further information, please contact

E-mail address

bpcrs@mhra.gov.uk

#### 1.4. Emergency telephone number

**Emergency Telephone** 

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

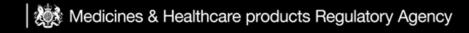
Emergency Telephone - §45 - (EC)1272/2008			
Europe	112		
Austria	No information available		
Bulgaria			
Croatia			
Cyprus			
Czech Republic			
Denmark			
France			
Hungary			
Ireland			
Italy			
Lithuania			
Luxembourg			
Netherlands			
Norway			
Portugal			
Romania			
Slovakia			
Slovenia			
Spain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

## **SECTION 2: Hazards identification**

## 2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

Acute toxicity - Oral	Category 4 - (H302)
Carcinogenicity	Category 2 - (H351)
Reproductive toxicity	Category 2 - (H361)
Acute aquatic toxicity	Category 1 - (H400)
Chronic aquatic toxicity	Category 1 - (H410)





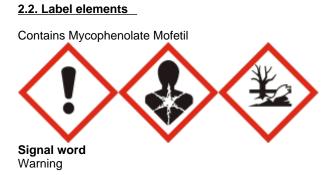
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#### Hazard statements

- H302 Harmful if swallowed
- H335 May cause respiratory irritation
- H336 May cause drowsiness or dizziness
- H351 Suspected of causing cancer
- H361d Suspected of damaging the unborn child
- H410 Very toxic to aquatic life with long lasting effects

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

- P201 Obtain special instructions before use
- P264 Wash face, hands and any exposed skin thoroughly after handling
- P273 Avoid release to the environment
- P280 Wear protective gloves/protective clothing/eye protection/face protection
- P391 Collect spillage
- P501 Dispose of contents/ container to an approved waste disposal plant

#### 2.3. Other hazards

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

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
Mycophenolate Mofetil	-	_

# SECTION 3: Composition/information on ingredients

3.1 Substances





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Chemical name	Weight-%	<b>REACH</b> registration	EC No (EU	Classification according		M-Factor	M-Factor
		number	Index No)	to Regulation (EC) No.	concentration		(long-term)
				1272/2008 [CLP]	limit (SCL)		
Mycophenolate	90 -	-	627-027-6	Acute Tox. 4 (H302)			
Mofetil	100%			Carc. 2 (H351)			
128794-94-5				Repr. 2 (H361d)			
				STOT SE 3 (H335)			
				STOT SE 3 (H336)			
				Aquatic Acute 1			
				(H400)			
				Aquatic Chronic 1			
				(H410)			

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

Acute Toxicity Estimate No information available

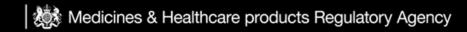
This product does not contain candidate substances of very high concern at a concentration >=0.1% (Regulation (EC) No. 1907/2006 (REACH), Article 59)

# 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.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a doctor.
Skin contact	Wash skin with soap and water. In the case of skin irritation or allergic reactions see a doctor.
Ingestion	Do NOT induce vomiting. Rinse mouth. Never give anything by mouth to an unconscious person. Call a doctor.

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





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Symptoms No information available.

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

**Note to doctors** Treat symptomatically.

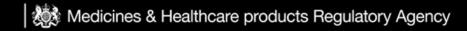
SECTION 5: Firefighting measures			
5.1. Extinguishing media			
Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.		
Large Fire	CAUTION: Use of water spray when fighting fire may be inefficient.		
Unsuitable extinguishing 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<br/>precautions for fire-fightersFirefighters should wear self-contained breathing apparatus and full firefighting turnout gear.<br/>Use personal protection equipment.

## **SECTION 6: Accidental release measures**

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

Personal precautions	Ensure adequate ventilation.		
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	See Section 12 for additional Ecological Information.		
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.
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. Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach of children. Store locked up.
7.3. Specific end use(s)	

#### 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**

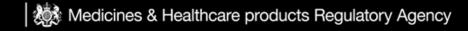
### 8.1. Control parameters

**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 regulatory bodies





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

8.2. Exposure controls

#### Personal protective equipment

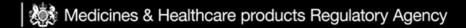
Eye/face protectionAvoid contact with eyes. Wear safety glasses with side shields (or goggles).Hand protectionThe protective gloves to be used must comply with the specifications of EC Directive<br/>89/686/EEC and the related standard EN374. Wear protective butyl rubber gloves. Wear<br/>suitable gloves.

Gloves				
Duration of contact	PPE - Glove material	Glove thickness	Break through time	
	Wear protective butyl			
	rubber gloves			
Skin and body protection	Wear suitable protective 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	No information available.
Odour threshold	No information available





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Property	Values	Remarks • Method
Melting point / freezing point	93 - 94 °C	None known
Initial boiling point and boiling rang	e637.6 °C	None known
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
pH	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	Insoluble in water 0.043 g/L	None known
Solubility(ies)	Chloroform, Methanol, slightly soluble	
Partition coefficient	2.5	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	433.49	
Molecular formula	C23H31NO7	

9.2.1. Information with regards to physical hazard classes Not applicable

9.2.2. Other safety characteristics No information available

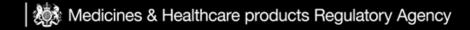
## SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity

No information available.

10.2. Chemical stability





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Stability

Stable under normal conditions.

**Explosion data** 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 None known based on information supplied.

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** 

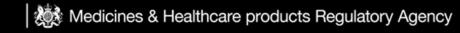
Inhalation	Specific test data for the substance or mixture is not available.
Eye contact	Specific test data for the substance or mixture is not available.
Skin contact	Specific test data for the substance or mixture is not available.
Ingestion	Specific test data for the substance or mixture is not available. Harmful if swallowed. (based on components).

#### Symptoms related to the physical, chemical and toxicological characteristics

Symptoms No information available.

Numerical measures of toxicity

Acute toxicity





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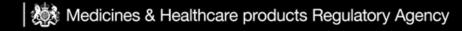
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Delayed and immediate effects as well as chronic effects from short and long-term exposure		
Skin corrosion/irritation	Based on available data, the classification criteria are not met.	
Serious eye damage/eye irritation	No information available.	
Respiratory or skin sensitisation	No information available.	
Germ cell mutagenicity	No information available.	
Carcinogenicity	Contains a known or suspected carcinogen. Classification based on data available for ingredients. Suspected of causing cancer.	
Reproductive toxicity	Contains a known or suspected reproductive toxin. Classification based on data available for ingredients. Suspected of damaging fertility or the unborn child.	
STOT - single exposure	May cause respiratory irritation. May cause drowsiness or dizziness.	
STOT - repeated exposure	No information available.	
Aspiration hazard	No information available.	
11.2. Information on other hazards	_	
11.2.1. Endocrine disrupting prope	erties	
Endocrine disrupting properties	No information available.	

11.2.2. Other information





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Other adverse effects

No information available.

## **SECTION 12: Ecological information**

## 12.1. Toxicity

Ecotoxicity

Very toxic to aquatic life with long lasting effects.

Chemical name	Algae/aquatic plants	Fish	Toxicity to	Crustacea
			microorganisms	
Mycophenolate Mofetil	-	-	-	EC50: > 100 mg/L (48h,
				Daphnia magna)

### 12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

**Bioaccumulation** 

No information available.

Chemical name	Partition coefficient
Mycophenolate Mofetil	2.5

### 12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

12.6. Endocrine disrupting properties

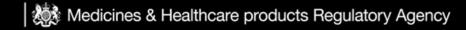
**Endocrine disrupting properties** No information available.

### 12.7. Other adverse effects

No information available.

# SECTION 13: Disposal considerations

13.1. Waste treatment methods





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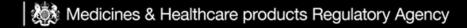
**Revision Number** 1

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Waste from residues/unused products	Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.
Contaminated packaging	Do not reuse empty containers.

# **SECTION 14: Transport information**

<ul> <li>IATA</li> <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 Description</li> <li>14.5 Environmental hazards</li> <li>14.6 Special precautions for user Special Provisions ERG Code</li> </ul>	UN3077 Environmentally hazardous substances, solid, n.o.s. (Mycophenolate Mofetil) 9 III UN3077, Environmentally hazardous substances, solid, n.o.s. (Mycophenolate Mofetil), 9, III Yes A97, A158, A179, A197, A215 9L
<ul> <li>IMDG</li> <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 Description</li> <li>14.5 Marine pollutant Environmental hazards</li> <li>14.6 Special precautions for user Special Provisions EmS-No</li> <li>14.7 Maritime transport in bulk according to IMO instruments</li> </ul>	UN3077 Environmentally hazardous substances, solid, n.o.s. (Mycophenolate Mofetil) 9 III UN3077, Environmentally hazardous substances, solid, n.o.s. (Mycophenolate Mofetil), 9, III, Marine pollutant P Yes 274, 335, 966, 967, 969 F-A, S-F No information available No information available
RID14.1 UN number or ID number14.2 UN proper shipping name14.3 Transport hazard class(es)14.4 Packing group Description14.5 Environmental hazards14.6 Special precautions for user Special Provisions	UN3077 Environmentally hazardous substances, solid, n.o.s. (Mycophenolate Mofetil) 9 III UN3077, Environmentally hazardous substances, solid, n.o.s. (Mycophenolate Mofetil), 9, III Yes 274, 335, 375, 601





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Classification code	M7
<u>ADR</u> 14.1 UN number or ID number 14.2 UN proper shipping name 14.3 Transport hazard class(es) 14.4 Packing group Description	UN3077 Environmentally hazardous substances, solid, n.o.s. (Mycophenolate Mofetil) 9 III UN3077, Environmentally hazardous substances, solid, n.o.s. (Mycophenolate Mofetil), 9,
14.5 Environmental hazards 14.6 Special precautions for user Special Provisions Classification code Tunnel restriction code	UII, (-) Yes 274, 335, 601, 375 M7 (-)

## **SECTION 15: Regulatory information**

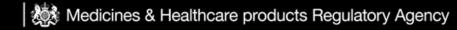
15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

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





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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)

# DIRECTIVE (EU) 2021/1187 on the marketing and use of explosives precursors

Not applicable

#### **Persistent Organic Pollutants**

Not applicable

#### Dangerous substance category per Seveso Directive (2012/18/EU)

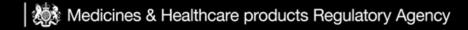
E1 - Hazardous to the Aquatic Environment in Category Acute 1 or Chronic 1

#### 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. Contact supplier for inventory compliance status Contact supplier for inventory compliance status

DSL/NDSL **EINECS/ELINCS** ENCS IECSC KECL PICCS AIIC





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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**

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

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

H302 - Harmful if swallowed

H335 - May cause respiratory irritation

H336 - May cause drowsiness or dizziness

H351 - Suspected of causing cancer

H361d - Suspected of damaging the unborn child

H400 - Very toxic to aquatic life

H410 - Very toxic to aquatic life with long lasting effects

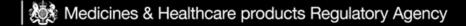
Legend

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





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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

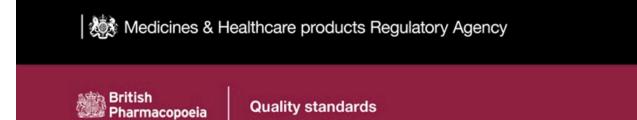
#### Key literature references and sources for data used to compile the SDS

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 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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# SAFETY DATA SHEET

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## CAT 1254 - Mycophenolate Mofetil

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