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# 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 21-Sep-2023

**Revision Number** 1

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

CAT 766
Caffeine Assay Standard

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)	200-362-1
CAS No	58-08-2
Chemical name	Caffeine
Pure substance/mixture	Substance
Formula	C8 H10 N4 O2
Molecular weight	194.19

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

**Recommended use** Laboratory use

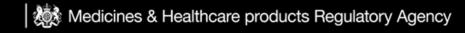
Uses advised against No information available

## 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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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)

## 2.2. Label elements

200-362-1 Contains Caffeine





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Warning

Hazard statements H302 - Harmful if swallowed

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

P264 - Wash face, hands and any exposed skin thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell
P330 - Rinse mouth
P501 - Dispose of contents/ container to an approved waste disposal plant

### 2.3. Other hazards

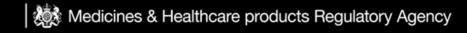
This substance does not meet the PBT/vPvB criteria of REACH, annex XIII.

Endocrine Disruptor Information This	roduct 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		
Caffeine	-	-		

# **SECTION 3: Composition/information on ingredients**

### 3.1 Substances

C	Chemical name	Weight-%	REACH registration number	· · ·	Classification according to Regulation (EC) No. 1272/2008 [CLP]	M-Factor	M-Factor (long-term)
	Caffeine 58-08-2	90 - 100%	-	200-362-1	Acute Tox. 4 (H302)		





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

#### Acute Toxicity Estimate

If LD50/LC50 data is not available or does not correspond to the classification category, then the appropriate conversion value from CLP Annex I, Table 3.1.2, is used to calculate the acute toxicity estimate (ATEmix) for classifying a mixture based on its components

Chemical name	Oral LD50 mg/kg	Dermal LD50	Inhalation LC50 - 4	Inhalation LC50 - 4	Inhalation LC50 - 4
		mg/kg	hour - dust/mist - mg/L	hour - vapour - mg/L	hour - gas - ppm
Caffeine	367.7	No data available	No data available	No data available	No data available
58-08-2					

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

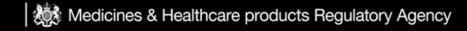
# SECTION 4: First aid measures

### 4.1. Description of first aid measures

General advice	Show this safety data sheet to the doctor in attendance.
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
Symptoms	No information available.
4.3. Indication of any immediate me	edical attention and special treatment needed

Note to doctors Treat symptomatically.

# **SECTION 5: Firefighting measures**





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## 5.1. Extinguishing media

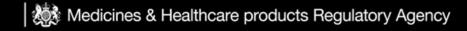
Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Large Fire	CAUTION: Use of water spray when fighting fire may be inefficient.
Unsuitable extinguishing media	Do not scatter spilled material with high pressure water streams.
5.2. Special hazards arising from th	e 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.
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 contai	inment and cleaning up
Methods for containment	Prevent further leakage or spillage if safe to do so.
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.





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SECTION 7: Handling and	SECTION 7: Handling and storage				
7.1. Precautions for safe handling					
Advice on safe handling	Ensure adequate ventilation.				
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.				
7.2. Conditions for safe storage, including 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.				
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

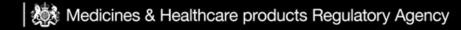
### Exposure Limits

Chemical name	European Union	Austria	Belgium	Bulgaria	Croatia
Caffeine	-	-	-	TWA: 0.5 mg/m <sup>3</sup>	-
58-08-2					
Chemical name	Ireland	Italy	Italy REL	Latvia	Lithuania
Caffeine	-	-	-	TWA: 0.5 mg/m <sup>3</sup>	TWA: 0.5 mg/m <sup>3</sup>
58-08-2					

## **Biological occupational exposure limits**

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies

# Derived No Effect Level (DNEL)No information available.Predicted No Effect ConcentrationNo information available.





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## (PNEC)

8.2. Exposure controls

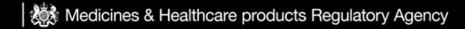
Eye/face protectionAvoid contact with eyes. Wear safety glasses with side shields (or goggles).Hand protectionWear protective nitrile rubber gloves. The protective gloves to be used must comply with the<br/>specifications of EC Directive 89/686/EEC and the related standard EN374.

Gloves			
Duration of contact	PPE - Glove material Glove thickness Break through tin		Break through time
	Wear protective nitrile 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.		
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 Crystalline Appearance Colour white Odour Odourless. **Odour threshold** No information available Property Remarks • Method Values Melting point / freezing point 238 °C None known Initial boiling point and boiling rangeNo data available None known Flammability No data available None known Flammability Limit in Air None known Upper flammability or explosive No data available





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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
рН	No data available	None known
pH (as aqueous solution)	5.5 - 6.5	@ 20 °C
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Water solubility	20 g/l	None known
Solubility(ies)	No data available	None known
Partition coefficient	-0.07	None known
Vapour pressure	No data available	None known
Relative density	1.23	@ 18 °C
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	194.19	
Molecular formula	C8 H10 N4 O2	

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.

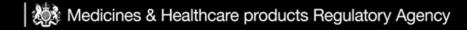
### 10.2. Chemical stability

Stability

Stable under normal conditions.

## Explosion data

Sensitivity to mechanical impact None. Sensitivity to static discharge None.





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None known based on information supplied.

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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

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).

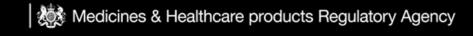
Symptoms related to the physical, chemical and toxicological characteristics

Symptoms No information available.

Numerical measures of toxicity

Acute toxicity

**Component Information** 





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Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Caffeine	= 367.7 mg/kg (Rat)	>2000 mg/kg bw (Rat)	
Delayed and immediate effects	as well as chronic effects fron	n short and long-term exposure	<u>)</u>
Skin corrosion/irritation	Based on available data, th	ne classification criteria are not m	et.
Serious eye damage/eye irritati	on No information available.		
Respiratory or skin sensitisatio	n No information available.		
Germ cell mutagenicity	No information available.		
Carcinogenicity	No information available.		
Reproductive toxicity	No information available.		
STOT - single exposure	No information available.		
STOT - repeated exposure	No information available.		
Aspiration hazard	No information available.		
11.2. Information on other haz	ards		
11.2.1. Endocrine disrupting p	roperties		
Endocrine disrupting propertie	s No information available.		
11.2.2. Other information			

Other adverse effects No information available.

# **SECTION 12: Ecological information**





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## CAT 766 - Caffeine Assay Standard

### 12.1. Toxicity

### Ecotoxicity

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Caffeine	-	LC50: =151mg/L (96h, Pimephales promelas)	-	-

### 12.2. Persistence and degradability

Persistence and degradability	No information available.
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### 12.3. Bioaccumulative potential

**Bioaccumulation** 

There is no data for this product.

#### **Component Information**

Chemical name	Partition coefficient
Caffeine	-0.07

#### 12.4. Mobility in soil

Mobility in soil

No information available.

### 12.5. Results of PBT and vPvB assessment

#### PBT and vPvB assessment

Chemical name	PBT and vPvB assessment
Caffeine	The substance is not PBT / vPvB

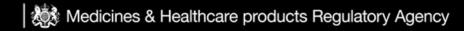
## 12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

#### 12.7. Other adverse effects

No information available.

# **SECTION 13: Disposal considerations**





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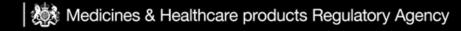
### 13.1. Waste treatment methods

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**

## <u>IATA</u>

<ul> <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</li> <li>14.5 Environmental hazards</li> <li>14.6 Special precautions for user Special Provisions</li> </ul>	Not regulated Not regulated Not regulated Not applicable None
IMDG	
14.1 UN number or ID number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Marine pollutant	Not applicable
14.6 Special precautions for user Special Provisions	None No information available
14.7 Maritime transport in bulk	No information available
according to IMO instruments	
5	
RID	
14.1 UN number or ID number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazards	Not applicable
14.6 Special precautions for user Special Provisions	None
Special Flovisions	None
ADR	
14.1 UN number or ID number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazards	Not applicable
14.6 Special precautions for user	





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Special Provisions None

# **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)

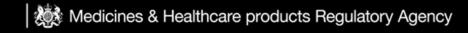
slightly hazardous to water (WGK 1)

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 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.





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#### 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

Ozone-depleting substances (ODS) regulation (EC) 1005/2009 Not applicable

International Inventories	
TSCA	Complies
DSL/NDSL	Contact supplier for inventory compliance status
EINECS/ELINCS	Contact supplier for inventory compliance status
ENCS	Contact supplier for inventory compliance status
IECSC	Contact supplier for inventory compliance status
KECL	Contact supplier for inventory compliance status
PICCS	Contact supplier for inventory compliance status
AIIC	Contact supplier for inventory compliance status

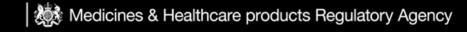
Leaend:

**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 has been carried out for this substance





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STEL (Short Term Exposure Limit)

Skin designation

## CAT 766 - Caffeine Assay Standard

# 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

#### Legend

SVHC: Substances of Very High Concern for Authorisation:

#### Legend Section 8: Exposure controls/personal protection

TWA	TWA (time-weighted average)	STEL
Ceiling	Maximum limit value	*

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		
Serious eye damage/eye irritation	Calculation method		
Respiratory sensitisation	Calculation method		
Skin sensitisation	Calculation method		
Mutagenicity	Calculation method		
Carcinogenicity	Calculation method		
Reproductive toxicity	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)

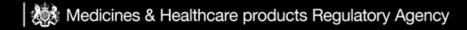
U.S. Environmental Protection Agency ChemView Database

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





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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

Revision date 21-Sep-2023

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006 Disclaimer

The information in this safety data sheet (SDS) has been prepared with due care and is true and accurate to the best of our knowledge. The user must determine the suitability of the information for its particular purpose, ensure compliance with existing laws and regulations, and be aware that other or additional safety or performance considerations may arise when using, handling and/ or storing the material. The information in this SDS does not purport to be all inclusive or a guarantee as to the properties of the material supplied, and should be used only as a guide. British Pharmacopoeia Commission Office makes no warranties or representations as to the accuracy and completeness of the information contained herein, shall not be heldresponsible for the suitability of this information for the user's intended purposes or the consequences of such use, and shall not be liable for any damage or loss, howsoever arising, direct or otherwise. End of Safety Data Sheet