

## 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 02-Jun-2023

**Revision Number** 1

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

1	.1.	Pr	oduct	identifier	

Product Code(s) CAT 937

**Product Name** Folic acid 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)	200-419-0
CAS No	59-30-3
Chemical name	Folic acid
Pure substance/mixture	Substance
Formula	C19 H19 N7 O6
Molecular weight	441.41

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

**Recommended use** Laboratory use

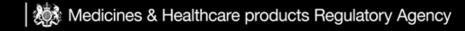
Uses advised against No information available

#### 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

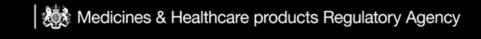
Regulation (EC) No 1272/2008

This substance is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

#### 2.2. Label elements

This substance is classified as not hazardous according to regulation (EC) 1272/2008 [CLP] Hazard statements

This substance is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]





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#### 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
Folic acid	-	-

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

#### 3.1 Substances

Chemical name	Weight-%	REACH registration number	· · ·	Classification according to Regulation (EC) No. 1272/2008 [CLP]	M-Factor	M-Factor (long-term)
Folic acid 59-30-3	90 - 100%	-	200-419-0	-		

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

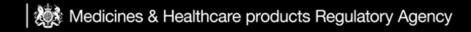
Acute Toxicity Estimate No information available

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

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





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	doctor.		
Ingestion	Rinse mouth.		
4.2. Most important symptoms and	effects, both acute and delayed		
Symptoms	No information available.		
4.3. Indication of any immediate me	dical attention and special treatment needed		
Note to doctors	Treat symptomatically.		
SECTION 5: Firefighting m	easures		
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.

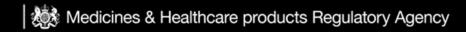
## SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Ensure adequate ventilation.

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions





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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.		
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	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.		
7.3. Specific end use(s)			

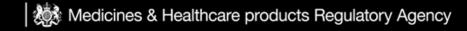
Risk Management Methods (RMM) The information required is contained in this Safety Data Sheet.

### 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.





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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 Concentration	No information available.
(PNEC)	

8.2. Exposure controls

Personal protective equipment

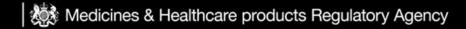
Eye/face protection Hand protection	Avoid contact with eyes. Wear safety glasses with side shields (or goggles). The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374. Wear protective nitrile rubber gloves.
Skin and body protection	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		
Appearance	Solid		
Colour	dark yellow		
Odour	No information available.		
Odour threshold	No information available		

Property	Values	
Melting point / freezing point	248 - 252 °C	
Initial boiling point and boiling rangeNo data available		
Flammability	No data available	

Remarks • Method None known None known None known





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data available	None known
data available	Nama Imayun
	None known
25 g/cm3	None known
data available	
data available	
data available	None known
information available	
information available	
1.41	
))))	o information available o information available 1.41 9 H19 N7 O6

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

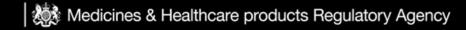
No information available.

10.2. Chemical stability

Stability

Stable under normal conditions.

Explosion data Sensitivity to mechanical impact None.





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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

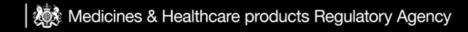
**Product Information** 

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.	
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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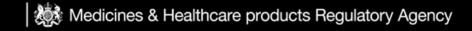
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Chemical name	Oral LD50	Dermal LD50	Inhalation LC50	
Folic acid	= 10,000 mg/kg (mouse)			
Delayed and immediate effects	Delayed and immediate effects as well as chronic effects from short and long-term exposure			
Skin corrosion/irritation	Based on available data,	the classification criteria are not m	net.	
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 haza	ards			
11.2.1. Endocrine disrupting properties				
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 937 - Folic acid Assay Standard

12.1. Toxicity		
Ecotoxicity	The environmental impact of this product has not been fully investigated.	
12.2. Persistence and degradability	,	
12.2. Fersistence and degradability		
Persistence and degradability	No information available.	
12.3. Bioaccumulative potential		
Bioaccumulation	No information available.	
12.4. Mobility in soil		
Mobility in soil	No information available.	
12.5. Results of PBT and vPvB ass	essment	
PBT and vPvB assessment	The product does not contain any substance(s) classified as PBT or vPvB.	
126 Endeering discuting	4iaa	
12.6. Endocrine disrupting properties		
Endocrine disrupting properties	No information available.	

#### 12.7. Other adverse effects

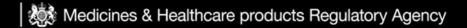
No information available.

## SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

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**





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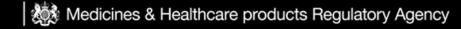
### CAT 937 - Folic acid Assay Standard

Not regulated Not regulated Not regulated Not regulated Not applicable
None
Not regulated Not regulated Not regulated Not regulated Not applicable None No information available No information available
Not regulated Not regulated Not regulated Not regulated Not applicable None
Not regulated Not regulated Not regulated Not regulated Not applicable None

## **SECTION 15: Regulatory information**

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

National regulations





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Water hazard class (WGK)

non-hazardous to water (nwg)

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.

#### 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





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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

#### 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 has been carried out for this substance

### SECTION 16: Other information

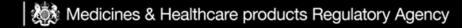
#### Key or legend to abbreviations and acronyms used in the safety data sheet

#### Legend

SVHC: Substances of Very High Concern for Authorisation:

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

TWĂ	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	*	Skin designation





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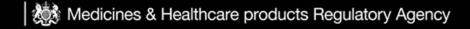
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Classification procedure	
Classification according to Regulation (EC) No. 1272/2008 [CLP]	Method Used
Acute oral toxicity	Calculation method
Acute dermal toxicity	Calculation method
Acute inhalation toxicity - gas	Calculation method
Acute inhalation 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 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

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