

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 17-Nov-2023

**Revision Number** 1

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

1.1. Product identifier	
Product Code(s)	CAT 923
Product Name	Calcium Folinate

Form Not applicable

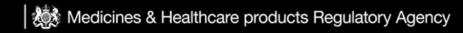
NOTE [8] - No registration number is given for this substance because it is under the threshold in REACH Article 6(1) and not subject to the registration requirements according to REACH Title II

EC No (EU Index No)	216-082-8			
CAS No.	1492-18-8			
Pure substance/mixture	Substance			
Formula	C20 H21 N7 O7 . Ca			
Molecular weight	511.50			
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 sa	fety data sheet			
<u>Supplier</u>				
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

For further information, please contact





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### CAT 923 - Calcium Folinate

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

Classification according to

Regulation (EC) No. 1272/2008 [CLP]

Skin corrosion/irritation	Category 2 - (H315)
Serious eye damage/eye irritation	Category 2 - (H319)
Respiratory sensitisation	Category 1 - (H334)
Skin sensitisation	Category 1 - (H317)





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Specific target organ toxicity — single exposure	Category 3 - (H335)
Category 3 Respiratory irritation	

#### 2.2. Label elements

Contains Calcium folinate



Signal word Danger

#### Hazard statements

H315 - Causes skin irritation

- H317 May cause an allergic skin reaction
- H319 Causes serious eye irritation
- H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled
- H335 May cause respiratory irritation

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

P261 - Avoid breathing dust/fume/gas/mist/vapours/spray

P264 - Wash face, hands and any exposed skin thoroughly after handling

- P280 Wear protective gloves and eye/face protection
- P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing

P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor

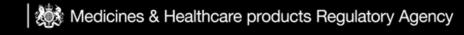
#### 2.3. Other hazards

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

ocrine Disruptor Information	This product does not contain any know	n or suspected endocrine disruptors.
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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
Calcium folinate	-	-

End





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# SECTION 3: Composition/information on ingredients

#### 3.1 Substances

Chemical name	Weight-%	REACH registration number		Classification according to Regulation (EC) No.		M-Factor	M-Factor (long-term)
			,	1272/2008 [CLP]	limit (SCL)		( 3 /
Calcium folinate	90 -	-	216-082-8	Skin Irrit. 2 (H315)			
1492-18-8	100%			Eye Irrit. 2 (H319)			
				Resp. Sens. 1 (H334)			
				Skin Sens. 1 (H317)			
				STOT SE 3 (H335)			

### 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

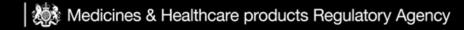
Chemical name	Oral LD50 mg/kg		Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapour - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Calcium folinate 1492-18-8	8000	No data available	No data available	No data available	No data available

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.
Inhalation	May cause allergic respiratory reaction. If breathing has stopped, give artificial respiration. Get medical attention immediately. Remove to fresh air. Avoid direct contact with skin. Use





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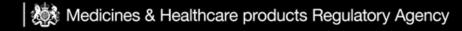
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	barrier to give mouth-to-mouth resuscitation. Get immediate medical attention.	
Eye contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Keep eye wide open while rinsing. Do not rub affected area. Get medical attention if irritation develops and persists.	
Skin contact	May cause an allergic skin reaction. In the case of skin irritation or allergic reactions see a doctor. Wash off immediately with soap and plenty of water for at least 15 minutes.	
Ingestion	May produce an allergic reaction. Do NOT induce vomiting. Rinse mouth. Never give anything by mouth to an unconscious person. Get immediate medical attention.	
Self-protection of the first aider	Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination. Avoid contact with skin, eyes or clothing. Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation. Use personal protective equipment as required. See section 8 for more information.	
4.2. Most important symptoms and	effects, both acute and delayed	
Symptoms	May cause allergy or asthma symptoms or breathing difficulties if inhaled. Coughing and/ or wheezing. Itching. Rashes. Hives. May cause redness and tearing of the eyes. Burning sensation.	
4.3. Indication of any immediate me	edical attention and special treatment needed	
Note to doctors	May cause sensitisation in susceptible persons. Treat symptomatically.	
SECTION 5: Firefighting m	leasures	
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	Product is or contains a sensitiser. May cause sensitisation by inhalation and skin contact. May cause sensitisation by skin contact.	





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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**

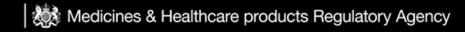
#### 6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions	Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak.	
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	Prevent further leakage or spillage if safe to do so.	
6.3. Methods and material for contai	nment 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 Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Provide extract ventilation to points where emissions occur. In case of insufficient ventilation, wear suitable respiratory





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	equipment. Do not eat, drink or smoke when using this product. Remove contaminated clothing and shoes. Take off contaminated clothing and wash it before reuse. Avoid breathing vapours or mists.		
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. Remove and wash contaminated clothing and gloves, including the inside, before re-use.		
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. Store locked up. 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** 

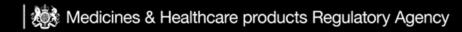
This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

#### **Biological occupational exposure limits**

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

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

8.2. Exposure controls





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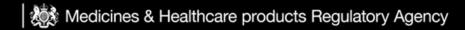
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Personal protective equipment			
Eye/face protection	Avoid contact with eyes. Wear safety glasses with side shields (or goggles).		
Hand protection	The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374. Polyvinyl chloride (PVC). Wear suitable gloves. Impervious gloves.		
Skin and body protection	Wear suitable protective clothing. Long sleeved 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. Remove and wash contaminated clothing and gloves, including the inside, before re-use.		
Environmental exposure controls	Do not allow into any sewer, on the ground or into any body of water.		

# SECTION 9: Physical and chemical properties

<u>9.1. Information on basic physical a</u> Physical state Appearance Colour Odour Odour threshold	nd chemical properties Solid Crystalline powder light yellow No information available. No information available	
Property Melting point / freezing point Initial boiling point and boiling rang Flammability Flammability Limit in Air Upper flammability or explosive limits Lower flammability or explosive	<u>Values</u> 240 - 250 °C eNo data available No data available No data available No data available	Remarks • Method None known None known None known None known
limits Flash point	No data available	None known





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Autoignition temperature	No data available	None known
Decomposition temperature		None known
рН	2.8 - 3	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	No data available	None known
Solubility(ies)	No data available	None known
Partition coefficient	No data available	None known
Vapour pressure	No data available	None known
Relative density	No data available	None known
Bulk density	0.5	
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	511.50	
Molecular formula	C20 H21 N7 O7 . Ca	

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.

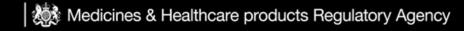
10.2. Chemical stability

Stability

Stable under normal conditions.

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

10.3. Possibility of hazardous reactions





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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	Strong acids. Strong bases. Strong oxidising agents.	
Hazardous decomposition products None known based on information supplied.		

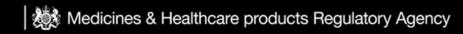
# **SECTION 11: Toxicological information**

#### 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. May cause sensitisation in susceptible persons. (based on components). May cause irritation of respiratory tract.	
Eye contact	Specific test data for the substance or mixture is not available. Causes serious eye irritation. (based on components). May cause redness, itching, and pain.	
Skin contact	Specific test data for the substance or mixture is not available. Repeated or prolonged skin contact may cause allergic reactions with susceptible persons. (based on components). May cause sensitisation by skin contact. Causes skin irritation.	
Ingestion	Specific test data for the substance or mixture is not available. May cause additional affects as listed under "Inhalation". Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhoea.	
Symptoms related to the physical, chemical and toxicological characteristics		
Symptoms	Symptoms of allergic reaction may include rash, itching, swelling, trouble breathing, tingling of the hands and feet, dizziness, lightheadedness, chest pain, muscle pain, or flushing. Coughing and/ or wheezing. Itching. Rashes. Hives. Redness. May cause redness and tearing of the eyes.	





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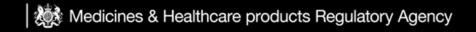
#### Numerical measures of toxicity

#### Acute toxicity

П

#### **Component Information**

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50	
Calcium folinate	> 8 g/kg (Rat)			
Delayed and immediate effects as well as chronic effects from short and long-term exposure				
Skin corrosion/irritation	Classification based on da irritation.	Classification based on data available for ingredients. Causes skin irritation. May cause skin irritation.		
Serious eye damage/eye irritati	on Classification based on da	Classification based on data available for ingredients. Causes serious eye irritation.		
Respiratory or skin sensitisatio	May cause allergy or asth allergic skin reaction.	May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.		
Germ cell mutagenicity	No information available.	No information available.		
Carcinogenicity	No information available.			
Reproductive toxicity	No information available.			
STOT - single exposure	May cause respiratory irrit	ation.		
STOT - repeated exposure	No information available.			





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Aspiration hazard No information available.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.

11.2.2. Other information

Other adverse effects No information available.

## **SECTION 12: Ecological information**

#### 12.1. Toxicity

**Ecotoxicity** The environmental impact of this product has not been fully investigated.

### 12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation No information available.

12.4. Mobility in soil

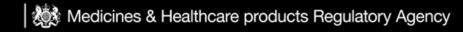
Mobility in soil No information available.

#### 12.5. Results of PBT and vPvB assessment

**PBT and vPvB assessment** This substance is not considered to be persistent, bioaccumulating nor toxic (PBT). This substance is not considered to be very persistent nor very bioaccumulating (vPvB).

Chemical name	PBT and vPvB assessment
Calcium folinate	The substance is not PBT / vPvB

### 12.6. Endocrine disrupting properties





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Endocrine disrupting properties No information available.

12.7. Other adverse effects No information available.

# SECTION 13: Disposal considerations

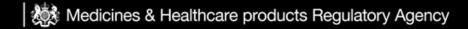
#### 13.1. Waste treatment methods

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**

IA	ТΑ
14	1

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
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	
<u>RID</u>	
14.1 UN number or ID number	Not regulated





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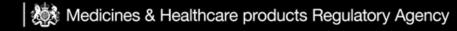
14.3 14.4 14.5	UN proper shipping name Transport hazard class(es) Packing group Environmental hazards Special precautions for user	Not regulated Not regulated Not regulated Not applicable
S	pecial Provisions	None
14.3 14.4 14.5	UN number or ID number UN proper shipping name Transport hazard class(es) Packing group Environmental hazards Special precautions for user	Not regulated Not regulated Not regulated Not regulated Not applicable
	pecial Provisions	None

# **SECTION 15: Regulatory information**

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

#### National regulations

Remarks This substance is considered a controlled drug in some countries and needs to be treated according to the applicable regulations Germany 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





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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:

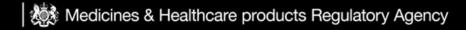
This product does not contain substances subject to authorisation (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

#### **DIRECTIVE (EU) 2021/1187 on the marketing and use of explosives precursors** Not applicable

Persistent Organic Pollutants Not applicable

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

Complies under research and development exemption or is regulated by a different





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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

H315 - Causes skin irritation

H317 - May cause an allergic skin reaction

H319 - Causes serious eye irritation

H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

H335 - May cause respiratory irritation

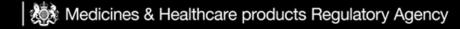
#### Legend

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 L
Ceiling	Maximum limit value	Sk*	Skin designation

Limit)





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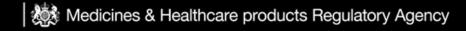
Revision Number 1

### CAT 923 - Calcium Folinate

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





# SAFETY DATA SHEET

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### CAT 923 - Calcium Folinate

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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