

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 27-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 843

**Product Name** Allopurinol Impurity C

Not applicable Form

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

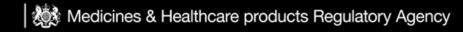
EC No (EU Index No)	-	
CAS No.	1346604-13-4	
Pure substance/mixture	Substance	
Formula	C6H6N6O	
Molecular weight	178.15	
1.2. Relevant identified uses of the	substance or mixture and uses advised against	
Recommended use	Laboratory use	
Uses advised against	No information available	
1.3. Details of the supplier of the safety data sheet		
Supplier		

<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 843 - Allopurinol Impurity C

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]

Acute toxicity - Oral	Category 4 - (H302)
Skin sensitisation	Category 1 - (H317)

#### 2.2. Label elements





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Contains Allopurinol Impurity C



Signal word Warning

Hazard statements H302 - Harmful if swallowed H317 - May cause an allergic skin reaction

#### 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

P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention

P501 - Dispose of contents/ container to an approved waste disposal plant

### 2.3. Other hazards

No information available.

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

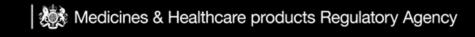
#### **Endocrine Disruptor Information** This product does not contain any known or suspected endocrine disruptors.

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
Allopurinol Impurity C	-	-

# SECTION 3: Composition/information on ingredients

### 3.1 Substances

Chemical name Weight-% REACH registration	EC No (EU Classification according	g Specific	M-Factor M-	-Factor
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	number	Index No)	to Regulation (EC) No. 1272/2008 [CLP]	concentration limit (SCL)	(long-term)
200 - 00 - 00 - 00 - 00 - 00 - 00 - 00	-	-	Acute Tox. 4 (H302) Skin Sens. 1 (H317)		

#### 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.
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 with soap and water. May cause an allergic skin reaction. 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.

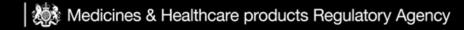
#### 4.2. Most important symptoms and effects, both acute and delayed

Symptoms Itching. Rashes. Hives.

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

**Note to doctors** May cause sensitisation in susceptible persons. Treat symptomatically.

# SECTION 5: Firefighting measures





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#### 5.1. Extinguishing media

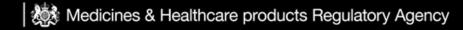
Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Large Fire	CAUTION: Use of water spray when fighting fire may be inefficient.
Unsuitable extinguishing media	Do not scatter spilled material with high pressure water streams.
5.2. Special hazards arising from th	e substance or mixture
Specific hazards arising from the chemical	Product is or contains a sensitiser. May cause sensitisation by skin contact.
5.3. Advice for firefighters	
Special protective equipment and	Firefighters should wear self contained breathing apparatus and full firefighting turnout gear

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.	
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 conta	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.	





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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. In case of insufficient ventilation, wear suitable respiratory equipment. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash it before reuse. 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** Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach of children. 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

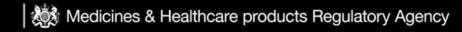
#### 8.1. Control parameters

Exposure Limits

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

#### **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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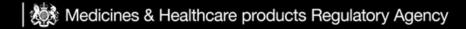
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Derived No Effect Level (DNEL) Predicted No Effect Concentration (PNEC)	No information available. No information available.
8.2. Exposure controls	
Personal protective equipment	
Eye/face protection	Avoid contact with eyes. Wear safety glasses with 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.
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	off-white				
Odour	No information available.				
Odour threshold	No information available				
<u>Property</u> Melting point / freezing point	<u>Values</u> No data available	Remarks • Method None known			





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Initial bailing point and bailing range	n la data available
Initial boiling point and boiling rang Flammability	No data available
Flammability Limit in Air	No data avallable
	No data available
Upper flammability or explosive limits	NO Uala avaliable
	No data available
Lower flammability or explosive	NO Uala avaliable
limits	No data available
Flash point	No data available
Autoignition temperature	No data avaliable
Decomposition temperature	
pH	No data available No data available
pH (as aqueous solution)	
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Water solubility	No data available
Solubility(ies)	No data available
Partition coefficient	No data available
Vapour pressure	No data available
Relative density	No data available
Bulk density	No data available
Liquid Density	No data available
Relative vapour density	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available
9.2. Other information	
Molecular weight	178.15
Molecular formula	C6H6N6O

None known None known None known

None known None known None known No information available None known None known

None known

9.2.1. Information with regards to physical hazard classes Not applicable

9.2.2. Other safety characteristics No information available

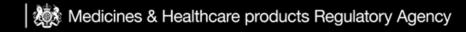
# **SECTION 10: Stability and reactivity**

#### 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**

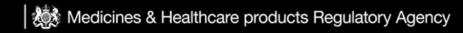
#### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

### 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	May cause sensitisation by 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).
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





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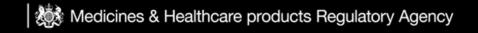
Symptoms

Itching. Rashes. Hives.

Numerical measures of toxicity No information available

Acute toxicity

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	May cause an allergic skin reaction.	
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 hazards		





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11.2.1.	Endocrine	disrupting	properties
11.4.1.	Endocrine	usrupting	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

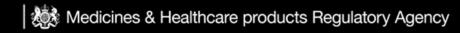
PBT and vPvB assessment

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	
Allopurinol Impurity C	The substance is not PBT / vPvB	

#### 12.6. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.





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12.7. Other adverse effects

No information available.

# **SECTION 13: Disposal considerations**

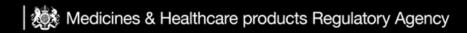
#### 13.1. Waste treatment methods

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**

#### <u>IATA</u>

	<u> </u>	
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
	Packing group	Not regulated
14.5	Environmental hazards	Not applicable
	Special precautions for user	
S	pecial Provisions	None
IMDO		
	UN number or ID number	Not regulated
	UN proper shipping name	Not regulated
	Transport hazard class(es)	Not regulated
	Packing group	Not regulated
	Marine pollutant	Not applicable
	Special precautions for user	
	pecial Provisions	None No information available
	Maritime transport in bulk	No information available
acco	rding to IMO instruments	
<u>RID</u>		
14.1	UN number or ID number	Not regulated
14.2	UN proper shipping name	Not regulated
	Transport hazard class(es)	Not regulated
14.4	33.1	Not regulated
14.5	Environmental hazards	Not applicable





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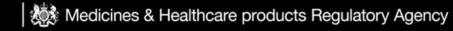
### CAT 843 - Allopurinol Impurity C

14.6 Special precautions for user Special Provisions	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	
Special Provisions	None

# **SECTION 15: Regulatory information**

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

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





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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

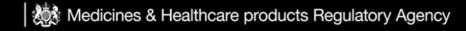
#### **Persistent Organic Pollutants**

Not applicable

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. DSL/NDSL Contact supplier for inventory compliance status **EINECS/ELINCS** Contact supplier for inventory compliance status ENCS Contact supplier for inventory compliance status Contact supplier for inventory compliance status **IECSC** Contact supplier for inventory compliance status KECL PICCS Contact supplier for inventory compliance status





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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 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

H317 - May cause an allergic skin reaction

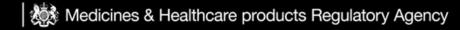
Legend

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	Sk*	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
Serious eye damage/eye irritation	Calculation method





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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

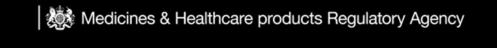
World Health Organization

**Revision date** 

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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





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