

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 24-Mar-2023

Revision Number 1

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

1.1. Product identifier				
Product Code(s)	CAT 042			
Product Name	Betamethasone Valerate Assay Standard			
Form	Not applicable			
	nber is given for this substance because it is under the threshold in REACH Article istration requirements according to REACH Title II			
EC No (EU Index No)	218-439-3			
CAS No	2152-44-5			
Chemical name	Betamethasone Valerate			
Pure substance/mixture	Substance			
Formula	C27H37FO6			
Molecular weight	476.64			
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

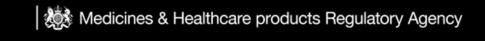
+44 (0)20 3080 6561 (Monday - Friday: 8am - 5pm)

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	
Reproductive toxicity	Category 1B - (H360D)
Specific target organ toxicity — repeated exposure	Category 2 - (H373)
Chronic aquatic toxicity	Category 2 - (H411)





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Danger

Hazard statements

H360D - May damage the unborn child H373 - May cause damage to organs through prolonged or repeated exposure H411 - Toxic to aquatic life with long lasting effects

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

P201 - Obtain special instructions before use

P260 - Do not breathe dust/fume/gas/mist/vapours/spray

P273 - Avoid release to the environment

P280 - Wear protective gloves/protective clothing/eye protection/face protection

P308 + P313 - IF exposed or concerned: Get medical advice/attention

P391 - Collect spillage

2.3. Other hazards

No information available.

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

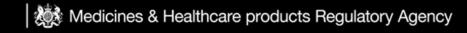
This product does not contain any known or suspected endocrine disruptors.

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
Betamethasone Valerate	-	-

SECTION 3: Composition/information on ingredients

3.1 Substances

Chemical name	Weight-%	REACH registration	EC No (EU	Classification according	Specific	M-Factor	M-Factor
	_	number	Index No)	to Regulation (EC) No.	concentration		(long-term)
				1272/2008 [CLP]	limit (SCL)		





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Betametnasone 90 - - 218-439-3 Repr. 1B (H360D) Valerate 100% STOT RE 2 (H373) Aquatic Chronic 2 (H411)		00	Aquatic Chronic 2		
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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		Inhalation LC50 - 4	Inhalation LC50 - 4	Inhalation LC50 - 4
		mg/kg	hour - dust/mist - mg/L	hour - vapour - mg/L	hour - gas - ppm
Betamethasone Valerate 2152-44-5	3000	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

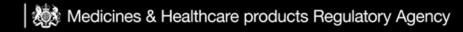
4.1. Description of first aid measures

General advice	Show this safety data sheet to the doctor in attendance.
Inhalation	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	Rinse mouth.
4.2 Most important symptoms and	effects, both acute and delayed

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

Symptoms No information available.

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





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 Note to doctors
 Treat symptomatically.

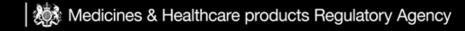
 SECTION 5: Firefighting measures

SECTION 5. Firengining measures				
5.1. Extinguishing media				
Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.			
Large Fire	CAUTION: Use of water spray when fighting fire may be inefficient.			
Unsuitable extinguishing media	Do not scatter spilled material with high pressure water streams.			
5.2. Special hazards arising from the	e substance or mixture			
Specific hazards arising from the chemical	No information available.			
5.3. Advice for firefighters				
Special protective equipment and precautions for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.			

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions	Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas.
Other information	Refer to protective measures listed in Sections 7 and 8.
For emergency responders	Use personal protection recommended in Section 8.
6.2. Environmental precautions	
Environmental precautions	See Section 12 for additional Ecological Information.
6.3. Methods and material for conta	ainment 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. Do not eat, drink or smoke when using this product. Remove contaminated clothing and shoes. 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. Wash hands before breaks and immediately after handling the product.
7.2. Conditions for safe storage, inc	luding 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. Store locked up.
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

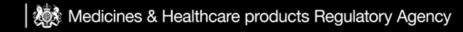
Exposure Limits

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.





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Predicted No Effect Concentration No information available. **(PNEC)**

8.2. Exposure controls

Personal protective equipment

 Eye/face protection
 Avoid contact with eyes. Wear safety glasses with side shields (or goggles).

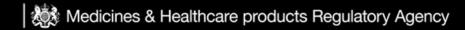
Hand protectionThe protective gloves to be used must comply with the specifications of EC Directive
89/686/EEC and the related standard EN374. Wear suitable gloves.

Gloves					
Duration of contact	PPE - Glove material	Break through time			
	Wear protective Viton™				
	gloves				
Skin and body protection	Wear suitable protective clothing.				
Respiratory protection	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.				
General hygiene considerations	Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Wash hands before breaks and after work. Wear suitable gloves and eye/face protection. Wash hands before breaks and immediately after handling the product.				
Environmental exposure controls	Do not allow into any sewer, on the ground or into any body of water.				

SECTION 9: Physical and chemical properties

Upper flammability or explosive No data available

9.1. Information on basic physica	l and chemical properties	
Physical state	Solid	
Appearance	Powder	
Colour	white	
Odour	No information available.	
Odour threshold	No information available	
Property	Values	Remarks • Method
Melting point / freezing point	188 °C	None known
Initial boiling point and boiling rai	ngeNo data available	None known
Flammability	No data available	None known
Flammability Limit in Air		None known





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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)	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)	Chloroform, Methanol, slightly soluble	
Partition coefficient	3.909	None known
Vapour pressure	No data available	None known
Relative density	No data available	None known
Bulk density	No data available	
Liquid Density	No data available	
Relative vapour density	No data available	None known
Particle characteristics		
Particle Size	No information available	
Particle Size Distribution	No information available	
9.2. Other information	170.04	
Molecular weight	476.64	
Molecular formula	C27H37FO6	

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

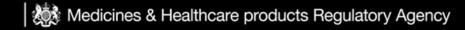
No information available.

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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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 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

Prod	luct	Inform	ation)

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

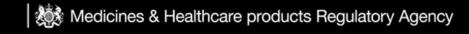
No information available.

Numerical measures of toxicity

Acute toxicity

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
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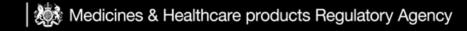
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Betamethasone Valerate	> 3 g/kg (Rat)	
Delayed and immediate effects as well as chronic effects from short and long-term exposure		
Skin corrosion/irritation	Based on available data, the classification criteria are not met.	
Serious eye damage/eye irritation	No information available.	
Respiratory or skin sensitisation	No information available.	
Germ cell mutagenicity	No information available.	
Carcinogenicity	No information available.	
Reproductive toxicity	Contains a known or suspected reproductive toxin. Classification based on data available for ingredients. May damage fertility or the unborn child.	
STOT - single exposure	No information available.	
STOT - repeated exposure	May cause damage to organs through prolonged or repeated exposure.	
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





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12.1. Toxicity

Ecotoxicity

Toxic to aquatic life with long lasting effects.

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation There is no data for this product.

Component Information

Chemical name	Partition coefficient
Betamethasone Valerate	3.909

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

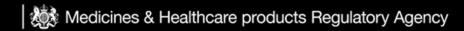
12.7. Other adverse effects

No information available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

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.





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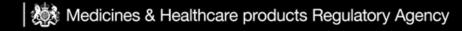
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SECTION 14: Transport information

 IATA 14.1 UN number or ID number 14.2 UN proper shipping name 14.3 Transport hazard class(es) 14.4 Packing group Description 14.5 Environmental hazards 14.6 Special precautions for user Special Provisions ERG Code 	UN3077 Environmentally hazardous substances, solid, n.o.s. (Betamethasone Valerate) 9 III UN3077, Environmentally hazardous substances, solid, n.o.s. (Betamethasone Valerate), 9, III Yes A97, A158, A179, A197, A215 9L
 IMDG 14.1 UN number or ID number 14.2 UN proper shipping name 14.3 Transport hazard class(es) 14.4 Packing group Description 14.5 Marine pollutant Environmental hazards 14.6 Special precautions for user Special Provisions EmS-No 14.7 Maritime transport in bulk according to IMO instruments 	UN3077 Environmentally hazardous substances, solid, n.o.s. (Betamethasone Valerate) 9 III UN3077, Environmentally hazardous substances, solid, n.o.s. (Betamethasone Valerate), 9, III, Marine pollutant P Yes 274, 335, 966, 967, 969 F-A, S-F No information available No information available
RID14.1 UN number or ID number14.2 UN proper shipping name14.3 Transport hazard class(es)14.4 Packing group Description14.5 Environmental hazards14.6 Special precautions for user Special Provisions Classification code	UN3077 Environmentally hazardous substances, solid, n.o.s. (Betamethasone Valerate) 9 III UN3077, Environmentally hazardous substances, solid, n.o.s. (Betamethasone Valerate), 9, III Yes 274, 335, 375, 601 M7
ADR 14.1 UN number or ID number 14.2 UN proper shipping name 14.3 Transport hazard class(es) 14.4 Packing group	UN3077 Environmentally hazardous substances, solid, n.o.s. (Betamethasone Valerate) 9 III





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Description	UN3077, Environmentally hazardous substances, solid, n.o.s. (Betamethasone Valerate), 9, III, (-)
14.5 Environmental hazards 14.6 Special precautions for user	Yes
Special Provisions	274, 335, 601, 375
Classification code	M7
Tunnel restriction code	(-)

SECTION 15: Regulatory information

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

National regulations

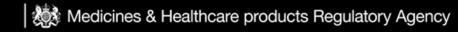
Germany

Water hazard class (WGK)

strongly hazardous to water (WGK 3)

Poland

SDS created according to the following Polish regulation: Act of February 25, 2011 on chemical substances and their mixtures (Journal of Laws of 2018, item 143, as amended). Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency (EC) as amended. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labeling and packaging of substances and mixtures, as amended. Regulation of the Minister of Health of 10 August 2012 on the criteria and method of classifying chemical substances and their mixtures (Journal of Laws of 2012, item 1018). Regulation of the Minister of Health of 20 April 2012 on labeling packaging of hazardous substances and mixtures and some mixtures (Journal of Laws of 2012, item 445). Regulation of the Minister of Family, Labor and Social Policy of 12 June 2018 on the maximum allowable concentrations and intensities of factors harmful to health in the work environment (Journal of Laws of 2018, item 1286). Announcement of the Minister of Economy, Labor and Social Policy of August 28, 2003 on the publication of the unified text of the Ordinance of the Minister of Labor and Social Policy on general health and safety at work regulations (Journal of Laws of 2003, No. 169, item 1650) . Regulation of the Minister of Health of 30 December 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).





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Government statement of September 24, 2002 - European Agreement on the International Carriage of Dangerous Goods by Road (ADR) (Journal of Laws No. 194, item 1629 and Journal of Laws of 2003, No. 207, item 2013 and 2014).

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

Authorisations and/or restrictions on use:

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

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

Persistent Organic Pollutants

Not applicable

Dangerous substance category per Seveso Directive (2012/18/EU) E2 - Hazardous to the Aquatic Environment in Category Chronic 2

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

International Inventories Complies under research and development exemption or is regulated by a different TSCA government agency. DSL/NDSL Contact supplier for inventory compliance status Contact supplier for inventory compliance status **EINECS/ELINCS** Contact supplier for inventory compliance status ENCS IECSC Contact supplier for inventory compliance status Contact supplier for inventory compliance status KECL PICCS Contact supplier for inventory compliance status Contact supplier for inventory compliance status AIIC

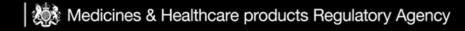
Legend:

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





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STEL (Short Term Exposure Limit)

Skin designation

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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

H360D - May damage the unborn child

H373 - May cause damage to organs through prolonged or repeated exposure

H411 - Toxic to aquatic life with long lasting effects

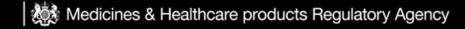
Legend

SVHC: Substances of Very High Concern for Authorisation:

Legend Section 8: Exposure controls/personal protection

TWATWA (time-weighted average)STELCeilingMaximum 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 STOT - single exposure Calculation method STOT - repeated exposure Calculation method Acute aquatic toxicity Calculation method Calculation method Chronic aquatic toxicity Aspiration hazard Calculation method Calculation method Ozone





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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

24-Mar-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