

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 20-Feb-2025 Revision Number 1.01

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

1.1. Product identifier

Product Code(s) CAT 007

Product Name alfaxalone

Form Not applicable

REACH registration number

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) 636-625-6

CAS No. 23930-19-0

Pure substance/mixture Substance

Formula C21 H32 O3

Molecular weight 332.53

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

Classification according to

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

Acute toxicity - Oral	Category 3 - (H301)
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2.2. Label elements

636-625-6 Contains Alphaxalone



Signal word Danger

Hazard statements

H301 - Toxic if swallowed.

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

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

P270 - Do not eat, drink or smoke when using this product

P301 + P310 - IF SWALLOWED: Immediately call a POISON CENTER or doctor

P330 - Rinse mouth

P501 - Dispose of contents and container in accordance with local, regional, national, and international regulations as applicable

2.3. Other hazards

PBT & vPvB 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)
- Candidate List of Substances of Very
High Concern (SVHC) for Authorisation

Alphaxalone

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

EU - REACH (1907/2006) - Endocrine
Disruptor Assessment List of
Substances

SECTION 3: Composition/information on ingredients

3.1 Substances

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Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	concentration	M-Factor	M-Factor (long-ter m)	Notes
Alphaxalone 23930-19-0	100	-	636-625-6	Acute Tox. 3 (H301)	-	-	-	-

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

<u>Acute Toxicity Estimate</u> 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 contactWash skin with soap and water. In the case of skin irritation or allergic reactions see a

doctor.

Ingestion Get medical attention.

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

Symptoms No information available.

Effects of ExposureNo information available.

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

Note to doctorsTreat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

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 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.

6.2. Environmental precautions

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.

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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.

Keep out of the reach of children.

Storage class (TRGS 510) LGK 6.1C.

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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Derived No Effect Level (DNEL) - Workers No information available

Derived No Effect Level (DNEL) - General Public No information available.

Predicted No Effect Concentration (PNEC) 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. 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

Appearance Solid Physical state Solid

Colourwhite, to, off-whiteOdourNo information availableOdour thresholdNo information available

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Property	Values_	Remarks • Method
Melting point / freezing point	173 - 175 °C	None known
Initial boiling point and boiling rang	eNo data available	None known
Flammability	No data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive	No data available	
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
SADT (°C)	No data available	None known
pH	No data available	None known
pH (as aqueous solution)	No data available	None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Water solubility	No data available None known	
Solubility(ies)	slightly soluble Ethyl acetate	
	Chloroform Methanol	
Partition coefficient	No data available	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	
0.2. Other information		
9.2. Other information	C21 H32 O3	
Molecular formula		
Molecular weight	332.53	

9.2.1. Information with regards to physical hazard classes

No information available

9.2.2. Other safety characteristics

No information available

SECTION 10: Stability and reactivity

10.1. Reactivity

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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

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 materialsNone known based on information supplied.

10.6. Hazardous decomposition products

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

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. Toxic if swallowed. (based on

components).

Symptoms related to the physical, chemical and toxicological characteristics

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Symptoms No information available.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Acute toxicity Toxic if swallowed.

Numerical measures of toxicity

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50	
Alphaxalone	= 297 mg/kg (Rat)	-	-	
Skin corrosion/irritation	Based on available data, the classification criteria are not met.			
Serious eye damage/eye irritation	on Based on available data, the classification criteria are not met.			

Respiratory or skin sensitisation Based on available data, the classification criteria are not met.

Germ cell mutagenicity Based on available data, the classification criteria are not met.

Carcinogenicity Based on available data, the classification criteria are not met.

Based on available data, the classification criteria are not met. Reproductive toxicity

STOT - single exposure Based on available data, the classification criteria are not met.

STOT - repeated exposure Based on available data, the classification criteria are not met.

Based on available data, the classification criteria are not met. **Aspiration hazard**

11.2. Information on other hazards

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11.2.1. Endocrine disrupting properties

Endocrine disrupting properties Based on available data, the classification criteria are not met.

11.2.2. Other information

Other adverse effects No information available.

SECTION 12: Ecological information

12.1. Toxicity

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

12.2. Persistence and degradability

Persistence and degradability

12.3. Bioaccumulative potential

No information available.

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 Based on available data, the classification criteria are not met.

12.6. Endocrine disrupting properties

Endocrine disrupting properties Based on available data, the classification criteria are not met.

12.7. Other adverse effects

No information available. Other adverse effects

Based on available data, the classification criteria are not met. PMT or vPvM properties

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.

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Contaminated packaging Do not reuse empty containers.

SECTION 14: Transport information

IATA

14.1 UN number or ID number UN2811

14.2 UN proper shipping name Toxic solid, organic, n.o.s. (Alphaxalone)

14.3 Transport hazard class(es) 6.1 14.4 Packing group Ш

Description UN2811, Toxic solid, organic, n.o.s. (Alphaxalone), 6.1, III

14.5 Environmental hazards

14.6 Special precautions for user

Special Provisions A3, A5 **ERG Code** 6L

IMDG

14.1 UN number or ID number UN2811

14.2 UN proper shipping name Toxic solid, organic, n.o.s. (Alphaxalone)

14.3 Transport hazard class(es) 14.4 Packing group

Description UN2811, Toxic solid, organic, n.o.s. (Alphaxalone), 6.1, III

14.5 Environmental hazards Νo

14.6 Special precautions for user **Special Provisions** 223, 274

EmS-No. F-A. S-A

14.7 Maritime transport in bulk according to IMO instruments

No information available

RID

14.1 UN number or ID number UN2811

14.2 UN proper shipping name Toxic solid, organic, n.o.s. (Alphaxalone)

14.3 Transport hazard class(es) 6.1 14.4 Packing group Ш

Description UN2811, Toxic solid, organic, n.o.s. (Alphaxalone), 6.1, III

14.5 Environmental hazards

14.6 Special precautions for user

274, 614 **Special Provisions** Classification code T2

ADR

14.1 UN number or ID number UN2811

Toxic solid, organic, n.o.s. (Alphaxalone) 14.2 UN proper shipping name

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14.3 Transport hazard class(es) 6.114.4 Packing group III

Description UN2811, Toxic solid, organic, n.o.s. (Alphaxalone), 6.1, III, (E)

14.5 Environmental hazards No

14.6 Special precautions for user

Special Provisions 274, 614
Classification code T2
Tunnel restriction code (E)

ADN

14.1 UN number or ID number UN2811

14.2 UN proper shipping name Toxic solid, organic, n.o.s. (Alphaxalone)

14.3 Transport hazard class(es)6.114.4 Packing group

Description UN2811, Toxic solid, organic, n.o.s. (Alphaxalone), 6.1, III

14.5 Environmental hazard No

14.6 Special precautions for user

Special Provisions 274, 614, 802

Classification code T2
Equipment Requirements PP, EP

SECTION 15: Regulatory information

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

National regulations

Germany

Water hazard class (WGK) slightly hazardous to water (WGK 1)

Chemical Prohibition Ordinance

(ChemVerbotsV)

This product is subject to requirements and restrictions regarding handling and delivery

TRGS 905 Not applicable

Switzerland

Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC) SR 814.018

Not applicable Storage of Hazardous Material

WPO (GSchV) SR 814.201; WPA (GSchG) SR 814.20

Class B

Major Accidents Ordinance SR 814.012

Not applicable

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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) 2024/590

Not applicable

International Inventories

TSCA LGC has not confirmed that the chemical substances in this product are on the TSCA

Inventory, and LGC is distributing this product solely for use either in applications statutorily exempt from TSCA and regulated under other laws (e.g., FFDCA, FIFRA) or in research and development activities in accordance with the TSCA Inventory R&D exemption provided

at 40 CFR 720.36. It is the end-user's responsibility to understand and follow the

requirements that apply to its use of this product.

DSL/NDSL
Contact supplier for inventory compliance status
EINECS/ELINCS
Contact supplier for inventory compliance status
ECSC
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
Contact supplier for inventory compliance status
AIIC
Contact supplier for inventory compliance status

Legend:

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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 Chemicals Inventory

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 any hazard and/or precautionary statements referred to under Sections 2-15

H301 - Toxic if swallowed

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

P270 - Do not eat, drink or smoke when using this product

P301 + P310 - IF SWALLOWED: Immediately call a POISON CENTER or doctor

P321 - Specific treatment (see supplemental first aid instructions on this label)

P330 - Rinse mouth

P405 - Store locked up

P501 - Dispose of contents and container in accordance with local, regional, national, and international regulations as applicable

Legend

Legena	
ACGIH	American Conference of Governmental Industrial Hygienists
AIDII	Italian Association of Industrial Hygienists
ADN	Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (Europe)
ADR	Agreement concerning the International Carriage of Dangerous Goods by Road (Europe)
AIIC	Australian Inventory of Industrial Chemicals
ATE	Acute Toxicity Estimate
ASTM	American Society for the Testing of Materials
bar	Biological Reference Values for Chemical Compounds in the Work Area
BAT	Biological tolerance values for occupational exposure
BEL	Biological exposure limits
bw	Body weight
Ceiling	Maximum limit value
CLP	Classification, Labelling and Packaging Regulation; Regulation (EC) No 1272/2008

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CMR	Carcinogen, Mutagen or Reproductive Toxicant
DFG	German Research Foundation
DOT	Department of Transportation (United States)
DSL	Domestic Substances List (Canada)
ECHA	European Chemicals Agency
EC Number	European Community number
EmS	Emergency Schedule
ENCS	Existing and New Chemical Substances (Japan)
EPA	Environmental Protection Agency
EWC	European Waste Codes
GHS	Globally Harmonized System
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IBC	International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk
ICAO	International Civil Aviation Organisation
IECSC	Inventory of Existing Chemical Substances in China
IMDG	International Maritime Dangerous Goods
IMO	International Maritime Organization
ISO	International Organisation for Standardisation
KECI	Korean Existing Chemicals Inventory
LC50	Lethal Concentration to 50% of a test population
LD50	Lethal Dose to 50% of a test population (Median Lethal Dose)
MAL	Measuring Technical Hygienic Air Needs
MARPOL	International Convention for the Prevention of Pollution from Ships
MDLPS	Ministry of Labour and Social Policy
n.o.s.	Not Otherwise Specified
NOAEC	No Observed Adverse Effect Concentration
NOAEL	No Observed Adverse Effect Level
NOELR	No Observable Effect Loading Rate
NZIoC	New Zealand Inventory of Chemicals
OECD	Organization for Economic Cooperation and Development
OEL	Occupational exposure limits
PBT	Persistent, Bioaccumulative and Toxic substance
PICCS	Philippines Inventory of Chemicals and Chemical Substances
PMT	Persistent, Mobile and Toxic
PPE	Personal protective equipment
QSAR	Quantitative Structure Activity Relationship
REACH	Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) Regulation (EC 1907/2006)
RID	Agreement concerning the International Carriage of Dangerous Goods by Rail (Europe)

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SADT	Self-Accelerating Decomposition Temperature	
SAR	Structure-activity relationship	
SDS	Safety Data Sheet	
SL	Surface Limit	
STEL	Short Term Exposure Limit	
STOT RE	Specific target organ toxicity - Repeated exposure	
STOT SE	Specific target organ toxicity - Single exposure	
SVHC	Substance of very high concern	
TCSI	Taiwan Chemical Substance Inventory	
TDG	Transport of Dangerous Goods (Canada)	
TRGS	Technical Rule for Hazardous Substances	
TSCA	Toxic Substances Control Act (United States)	
TWA	Time-Weighted Average	
UN	United Nations	
VOC	Volatile organic compounds	
vPvB	Very Persistent and Very Bioaccumulative	
vPvM	Very Persistent and Very Mobile	
Sen+	Sensitiser	
Sk*	Skin designation	
**	Hazard 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			
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			
Chronic aquatic toxicity	Calculation method			
Acute aquatic toxicity	Calculation method			
Aspiration hazard	Calculation method			

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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)

European Chemicals Agency (ECHA) Committee for Risk Assessment (ECHA_RAC)

European Chemicals Agency (ECHA) (ECHA_API)

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)

National Institute of Technology and Evaluation (NITE)

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)

U.S. 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

20-Feb-2025

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

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