

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 10-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 1248

Product Name Candesartan Cilexetil

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) 627-030-2

CAS No 145040-37-5

Chemical name Candesartan Cilexetil

Pure substance/mixture Substance

Formula C33H34N6O6

Molecular weight 610.7

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

EGHS / EN Page 1/16



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 10-Mar-2023 Revision Number 1

CAT 1248 - Candesartan Cilexetil

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 1A - (H360D)
Effects on or via lactation	Yes - (H362)
Specific target organ toxicity — repeated exposure	Category 2 - (H373)
Acute aquatic toxicity	Category 1 - (H400)
Chronic aquatic toxicity	Category 1 - (H410)



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Revision date 10-Mar-2023 Revision Number 1

CAT 1248 - Candesartan Cilexetil

2.2. Label elements

Contains Candesartan Cilexetil



Signal word Danger

Hazard statements

H360D - May damage the unborn child

H362 - May cause harm to breast-fed children

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

H410 - Very 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

P263 - Avoid contact during pregnancy and while nursing

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

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

Endocrine Disruptor Information	on 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			
Candesartan Cilexetil				

SECTION 3: Composition/information on ingredients

3.1 Substances



SAFETY DATA SHEET

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Revision date 10-Mar-2023 Revision Number 1

CAT 1248 - Candesartan Cilexetil

С	Chemical name	Weight-%	REACH registration number	,	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
	Candesartan Cilexetil 145040-37-5	90 - 100%	-	627-030-2	Repr. 1A (H360D) Lact. (H362) STOT RE 2 (H373) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)			

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 contactWash 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

Symptoms No information available.

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



SAFETY DATA SHEET

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Revision date 10-Mar-2023 Revision Number 1

CAT 1248 - Candesartan Cilexetil

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. Use personal protective equipment as required. Evacuate

personnel to safe areas.

Other information Refer to protective measures listed in Sections 7 and 8.

6.2. Environmental precautions

Environmental precautionsSee Section 12 for additional Ecological Information.

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning upTake 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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Revision date 10-Mar-2023 Revision Number 1

CAT 1248 - Candesartan Cilexetil

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, including any incompatibilities

Storage Conditions Please refer to the manufacturer's certificate for specific storage and transport temperature

conditions. Store only in the original receptacle unless other advice is given on the CoA.

7.3. Specific end use(s)

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

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure Limits This product, as supplied, does not contain any hazardous materials with occupational

exposure limits established by the region specific regulatory bodies.

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)
Predicted No Effect Concentration
(PNEC)

No information available. No information available.



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Revision date 10-Mar-2023 Revision Number 1

CAT 1248 - Candesartan Cilexetil

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 suitable gloves.

Gloves				
Duration of contact	PPE - Glove material	Glove thickness	Break through time	
Wear protective butyl				
	rubber gloves			

Skin and body protectionWear 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

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> <u>Values</u> <u>Remarks • Method</u>

Melting point / freezing point156 °CNone knownInitial boiling point and boiling rangeNo data availableNone knownFlammabilityNo data availableNone knownFlammability Limit in AirNone known

Upper flammability or explosive No data available

limits

Lower flammability or explosive No data available



SAFETY DATA SHEET

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Revision date 10-Mar-2023 Revision Number 1

CAT 1248 - Candesartan Cilexetil

limitsFlash pointNo data availableNone knownAutoignition temperatureNo data availableNone knownDecomposition temperatureNo data availableNone knownpHNo data availableNone known

pH (as aqueous solution)

No data available

No information available

None known

No data available

None known

 Dynamic viscosity
 No data available
 None known

 Water solubility
 No data available
 None known

 Solubility(ice)
 DMSO Methanol slightly soluble

Solubility(ies) DMSO, Methanol, slightly soluble

Partition coefficientNo data availableNone knownVapour pressureNo data availableNone knownRelative densityNo data availableNone known

Bulk density
No data available
No data available

Relative vapour density

No data available

None known

Particle characteristics

Particle SizeNo information availableParticle Size DistributionNo information available

9.2. Other information

Molecular weight 610.7

Molecular formula C33H34N6O6

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



SAFETY DATA SHEET

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Revision date 10-Mar-2023 Revision Number 1

CAT 1248 - Candesartan Cilexetil

10.4. Conditions to avoid

Conditions to avoid None known based on information supplied.

Possibility of hazardous reactions
None under normal processing.

10.5. Incompatible materials

Incompatible materialsNone known based on information supplied.

Hazardous decomposition products None known based on information supplied.

SECTION 11: Toxicological information

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

Information on likely routes of exposure

Product Information

Inhalation Specific test data for the substance or mixture is not available.

Eye contact Specific test data for the substance or mixture is not available.

Skin contact Specific test data for the substance or mixture is not available.

Ingestion Specific test data for the substance or mixture is not available.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms No information available.

Numerical measures of toxicity

Acute toxicity

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Candesartan Cilexetil	>2000 mg/kg (Rat)		



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 10-Mar-2023 Revision Number 1

CAT 1248 - Candesartan Cilexetil

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

Skin corrosion/irritationBased 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. May cause harm to breast-fed

children.

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

12.1. Toxicity



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 10-Mar-2023 Revision Number 1

CAT 1248 - Candesartan Cilexetil

Ecotoxicity

Very toxic to aquatic life with long lasting effects.

	Chemical name	Algae/aquatic plants	Fish	Toxicity to	Crustacea
				microorganisms	
Γ	Candesartan Cilexetil	EC50: >0.012 mg/L (72h,	LC50: >0.017 mg/L (96h,	-	EC50: >0.016 mg/L (48h,
		Algae)	Fish)		Daphnia magna)
		-			_

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 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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This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 10-Mar-2023 Revision Number 1

CAT 1248 - Candesartan Cilexetil

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. (Candesartan Cilexetil)

UN3077, Environmentally hazardous substances, solid, n.o.s. (Candesartan Cilexetil), 9, III

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

UN3077

Environmentally hazardous substances, solid, n.o.s. (Candesartan Cilexetil)

Yes

UN3077, Environmentally hazardous substances, solid, n.o.s. (Candesartan Cilexetil), 9,

III, Marine pollutant Ρ

14.5 Marine pollutant

Environmental hazards

14.6 Special precautions for user

EmS-No

Special Provisions

274, 335, 966, 967, 969

No information available

F-A, S-F No information available

A97, A158, A179, A197, A215

14.7 Maritime transport in bulk according to IMO instruments

RID

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**

Classification code

Environmentally hazardous substances, solid, n.o.s. (Candesartan Cilexetil)

Ш

UN3077, Environmentally hazardous substances, solid, n.o.s. (Candesartan Cilexetil), 9, III

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

Description

UN3077

Environmentally hazardous substances, solid, n.o.s. (Candesartan Cilexetil)

UN3077, Environmentally hazardous substances, solid, n.o.s. (Candesartan Cilexetil), 9,

III, (-)



SAFETY DATA SHEET

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Revision date 10-Mar-2023 Revision Number 1

CAT 1248 - Candesartan Cilexetil

14.5 Environmental hazards Yes

14.6 Special precautions for user

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). Government statement of September 24, 2002 - European Agreement on the International Carriage of Dangerous Goods by Road (ADR) (Journal of Laws No. 194,



SAFETY DATA SHEET

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Revision date 10-Mar-2023 Revision Number 1

CAT 1248 - Candesartan Cilexetil

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)

E1 - Hazardous to the Aquatic Environment in Category Acute 1 or Chronic 1

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

EINECS/ELINCS

Contact supplier for inventory compliance status
Contact supplier for inventory compliance status
ENCS

Contact supplier for inventory compliance status
IECSC

Contact supplier for inventory compliance status
KECL

Contact supplier for inventory compliance status
Contact supplier for inventory compliance status
Contact supplier for inventory compliance status
AllC

Contact supplier for inventory compliance status
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



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 10-Mar-2023 Revision Number 1

CAT 1248 - Candesartan Cilexetil

AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report A Chemical Safety Assessment has been carried out for this substance

SECTION 16: Other information

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

Full text of H-Statements referred to under section 3

H360D - May damage the unborn child

H362 - May cause harm to breast-fed children

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

H400 - Very toxic to aquatic life

H410 - Very toxic to aquatic life with long lasting effects

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 Limit)

Ceiling Maximum limit value * 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			
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			
Chronic aquatic toxicity	Calculation method			
Aspiration hazard	Calculation method			
Ozone	Calculation method			



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 10-Mar-2023 Revision Number 1

CAT 1248 - Candesartan Cilexetil

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 10-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