

# Medicines & Healthcare products Regulatory Agency

**British** Pharmacopoeia

**Quality standards** 

# **SAFETY DATA SHEET**

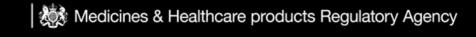
This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 03-May-2023

**Revision Number** 1

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

1.1. Product identifier	
Product Code(s)	CAT 1249
Product Name	Candesartan Impurity Standard
Form	Not applicable
Pure substance/mixture	Mixture
1.2. Relevant identified uses of the	substance or mixture and uses advised against
Recommended use	Laboratory use
Uses advised against	No information available
1.3. Details of the supplier of the sa	fety data sheet
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	
For further information, please contact	<u>t</u>
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	





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# **SECTION 2: Hazards identification**

2.1. Classification of the substance or mixture

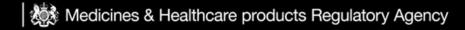
Regulation (EC) No 1272/2008

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)

### 2.2. Label elements

Contains Candesartan Cilexetil, Candesartan cilexetil impurity D EP







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#### 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 mixture contains no substance considered to be persistent, bioaccumulating or toxic (PBT). This mixture contains no substance considered to be very persistent nor very bioaccumulating (vPvB).

**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
Candesartan Cilexetil	-	-
Candesartan cilexetil impurity D EP	-	-

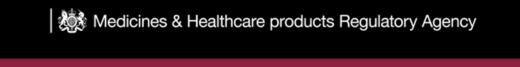
# SECTION 3: Composition/information on ingredients

### 3.1 Substances

Not applicable

### 3.2 Mixtures

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





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				(H400) Aquatic Chronic 1 (H410)		
Candesartan cilexetil impurity D EP 1185256-03-4	0 - 10%	-	-	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

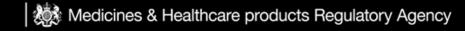
Acute Toxicity Estimate No information available

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 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	
Symptoms	No information available.	
4.3. Indication of any immediate medical attention and special treatment needed		
Note to doctors	Treat symptomatically.	





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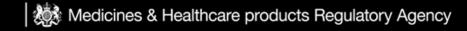
SECTION 5: Firefighting measures		
5.1. Extinguishing media		
Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.	
Large Fire	CAUTION: Use of water spray when fighting fire may be inefficient.	
Unsuitable extinguishing media	Do not scatter spilled material with high pressure water streams.	
5.2. Special hazards arising from th	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 containment and cleaning up		
Methods for containment	Prevent further leakage or spillage if safe to do so.	
Methods for cleaning up	Take up mechanically, placing in appropriate containers for disposal.	
Prevention of secondary hazards	Clean contaminated objects and areas thoroughly observing environmental regulations.	
6.4. Reference to other sections		





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See section 8 for more information. See section 13 for more information. Reference to other sections

# SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Handle in accordance with good industrial hygiene and safety practice. Avoid contact with Advice on safe handling 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 Wash hands before breaks and immediately after handling the product. 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 Please refer to the manufacturer's certificate for specific storage and transport temperature Storage Conditions 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** 

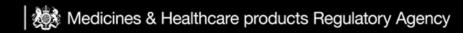
This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

### **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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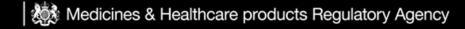
# CAT 1249 - Candesartan Impurity Standard

### 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. 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	Wash hands before breaks and immediately after handling the product. 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 a	and chemical properties	
Physical state	Solid	
Appearance	Solid	
Colour	off-white	
Odour	Odourless.	
Odour threshold	No information available	
Property_	Values_	Remarks • Method
Melting point / freezing point	No data available	None known
Initial boiling point and boiling rang	<b>je</b> No 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
· ·		





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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)	No data available	None known
Partition coefficient	No data available	None known
Vapour pressure	No data available	None known
Relative density	No data available	None known
Bulk density	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

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.

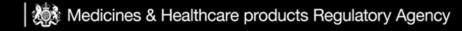
#### 10.3. Possibility of hazardous reactions

Possibility of hazardous reactions None under normal processing.

### 10.4. Conditions to avoid

**Conditions to avoid** 

None known based on information supplied.





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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	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
No information available

### Acute toxicity

# The following values are calculated based on chapter 3.1 of the GHS document<br/>ATEmix (oral)2,011.10 mg/kg

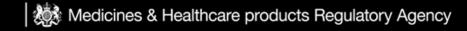
### **Component Information**

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Candesartan Cilexetil	>2000 mg/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.





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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 prope	rties	
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** Very toxic to aquatic life with long lasting effects.

Unknown aquatic toxicity Contains 0 % of components with unknown hazards to the aquatic environment.





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Chemical name	Algae/aquatic plants	Fish	Toxicity to	Crustacea
			microorganisms	
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

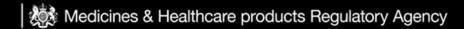
No information available.

# 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.

# **SECTION 14: Transport information**





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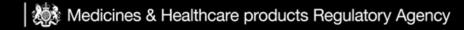
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<ul> <li>IATA <ul> <li>IATA</li> <li>14.1 UN number or ID number</li> <li>14.2 UN proper shipping name</li> </ul> </li> <li>14.3 Transport hazard class(es) <ul> <li>14.4 Packing group <ul> <li>Description</li> </ul> </li> <li>14.5 Environmental hazards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





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14.3 Transport hazard class(es)	9
14.4 Packing group	
Description	UN3077, Environmentally hazardous substances, solid, n.o.s. (Candesartan Cilexetil,
	Candesartan cilexetil impurity D EP), 9, III, (-)
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

Water hazard class (WGK)

non-hazardous to water (nwg)

Poland

SDS created according to the following Polish regulation: Act of February 25, 2011 on chemical substances and their mixtures (Journal of Laws of 2018, item 143, as amended). Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency (EC) as amended. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labeling and packaging of substances and mixtures, as amended. Regulation of the Minister of Health of 10 August 2012 on the criteria and method of classifying chemical substances and their mixtures (Journal of Laws of 2012, item 1018). Regulation of the Minister of Health of 20 April 2012 on labeling packaging of hazardous substances and mixtures and some mixtures (Journal of 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





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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)

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

Legend:

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

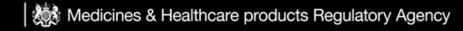
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

**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





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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

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:

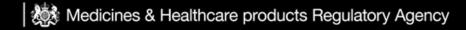
#### Legend Section 8: Exposure controls/personal protection

TWA TWA (time-weighted average) Ceiling Maximum limit value

STEL

STEL (Short Term Exposure Limit) 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	





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# CAT 1249 - Candesartan Impurity Standard

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

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This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006 Disclaimer

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