

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 27-Oct-2023

Revision Number 1

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

1.1. Product identifier	
Product Code(s)	CAT 777

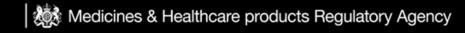
Product Name Felodipine Assay Standard

Not applicable Form

NOTE [8] - No registration number is given for this substance because it is under the threshold in REACH Article 6(1) and not subject to the registration requirements according to REACH Title II

EC No (EU Index No)	620-472-7
CAS No.	72509-76-3
Chemical name	Felodipine
Pure substance/mixture	Substance
Formula	C ₁₈ H ₁₉ C l ₂ NO ₄
Molecular weight	384.25
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
<u>Supplier</u>	
British Pharmacopoeia Commission MHRA 10 South Colonnade Canary Wharf London E14 4PU United Kingdom	
T_{O} + 14 (0)20 2020 6561	

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	

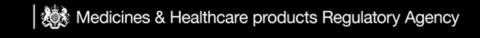
SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to

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

Acute toxicity - Oral	Category 4 - (H302)
Reproductive toxicity	Category 2 - (H361d)





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Acute aquatic toxicity Category 1 - (H400)

2.2. Label elements





Warning

Hazard statements

H302 - Harmful if swallowed H361d - Suspected of damaging the unborn child H400 - Very toxic to aquatic life

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

P201 - Obtain special instructions before use

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

P273 - Avoid release to the environment

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

P391 - Collect spillage

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

2.3. Other hazards

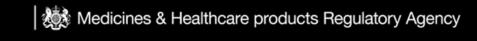
No information available.

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

Endocrine Disruptor Information	This product does not contain an	y known or suspected endocrine disruptors.
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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
Felodipine	-	-

SECTION 3: Composition/information on ingredients





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3.1 Substances

Chemical name	Weight-%	REACH registration number		Classification according to Regulation (EC) No. 1272/2008 [CLP]	•	M-Factor	M-Factor (long-term)
Felodipine 72509-76-3	90 - 100%	-	620-472-7	Acute Tox. 4 (H302) Repr. 2 (H361d) Aquatic Acute 1 (H400)			

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

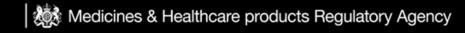
Chemical name	Oral LD50 mg/kg		Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapour - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Felodipine 72509-76-3	1050	No data available	No data available	No data available	No data available

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.





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Ingestion	Do NOT induce vomiting. Rinse mouth. Never give anything by mouth to an unconscious person. Call a doctor.	
4.2. Most important symptoms and	effects, both acute and delayed	
Symptoms	No information available.	
4.3. Indication of any immediate me	edical attention and special treatment needed	
Note to doctors	Treat symptomatically.	
SECTION 5: Firefighting m	easures	
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 substance or mixture

Specific hazards arising from the No information available. chemical

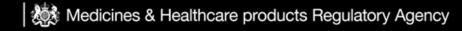
5.3. Advice for firefighters

Special protective equipment and
precautions for fire-fightersFirefighters 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.
For emergency responders	Use personal protection recommended in Section 8.





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6.2. Environmental precautions

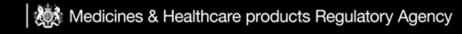
Environmental precautions	See Section 12 for additional Ecological Information.
6.3. Methods and material for containment and cleaning up	
Methods for containment	Prevent further leakage or spillage if safe to do so.
Methods for cleaning up	Take up mechanically, placing in appropriate containers for disposal.
Prevention of secondary hazards	Clean contaminated objects and areas thoroughly observing environmental regulations.
6.4. Reference to other sections	
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.
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	cluding 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 containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach of children. Store locked up.
7.3. Specific end use(s)	

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





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

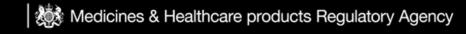
8.2. Exposure controls

Persona	l protective ec	quipment

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 Glove thickness Break through time		
	Wear protective nitrile	0.11 mm	480 minutes
	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. Wash hands before breaks and immediately after handling the product.		





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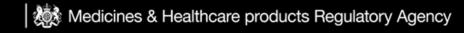
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Environmental exposure controls Do not allow into any sewer, on the ground or into any body of water.

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	No information available.	
Odour threshold	No information available	
Property_	Values	Remarks • Method
Melting point / freezing point	143 °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
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)	Acetone, Chloroform, Methanol	
Partition coefficient	3.86	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		
Molecular weight	384.25	





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Molecular formula C₁₈H₁₉Cl₂NO₄

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.

10.5. Incompatible materials

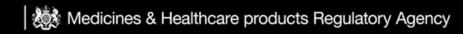
Incompatible materials None known based on information supplied.

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





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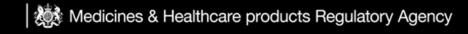
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Product Information		
Inhalation	Specific test data for the substance or mixture is not available.	
Eye contact	Specific test data for the substance or mixture is not available.	
Skin contact	Specific test data for the substance or mixture is not available.	
Ingestion	Specific test data for the substance or mixture is not available. Harmful if swallowed. (based on components).	
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
Felodipine	= 1050 mg/kg (Rat)		
Delayed and immediate effects a	as well as chronic effects from	n short and long-term exposu	re
Skin corrosion/irritation	Based on available data, t	he classification criteria are not r	net.
Serious eye damage/eye irritatio	n No information available.		
Respiratory or skin sensitisation	No information available.		
Germ cell mutagenicity	No information available.		
Carcinogenicity	No information available.		





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Reproductive toxicity	Contains a known or suspected reproductive toxin. Classification based on data available for ingredients. Suspected of damaging fertility or the unborn child.	
STOT - single exposure	No information available.	
STOT - repeated exposure	No information available.	
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

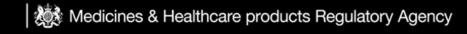
Ecotoxicity

Very toxic to aquatic life.

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Felodipine	EC50: > 0.332 mg/L (72h, green algae)	LC50: = 0.39 mg/L (96h, Pimephales promelas (fathead minnow))	-	LC50: = 0.62 mg/L (48h, Daphnia magna (Water flea))

12.2. Persistence and degradability

Persistence and degradability No information available.





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12.3. Bioaccumulative potential

Bioaccumulation

There is no data for this product.

Component Information

Chemical name	Partition coefficient
Felodipine	3.86

12.4. Mobility in soil

Mobility in soil

No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment

This substance is not considered to be persistent, bioaccumulating nor toxic (PBT). This substance is not considered to be very persistent nor very bioaccumulating (vPvB).

Chemical name	PBT and vPvB assessment	
Felodipine	The substance is not PBT / vPvB	

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

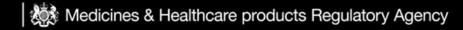
No information available.

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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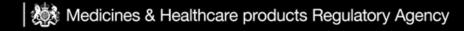
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IATA14.1UN number or ID number14.2UN proper shipping name14.3Transport hazard class(es)14.4Packing groupDescription14.5Environmental hazards14.6Special precautions for userSpecial ProvisionsERG Code	UN3077 Environmentally hazardous substances, solid, n.o.s. (Felodipine) 9 III UN3077, Environmentally hazardous substances, solid, n.o.s. (Felodipine), 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. (Felodipine) 9 III UN3077, Environmentally hazardous substances, solid, n.o.s. (Felodipine), 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. (Felodipine) 9 III UN3077, Environmentally hazardous substances, solid, n.o.s. (Felodipine), 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. (Felodipine) 9 III	





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Description 14.5 Environmental hazards 14.6 Special precautions for user	UN3077, Environmentally hazardous substances, solid, n.o.s. (Felodipine), 9, III, (-) 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





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December 14, 2012 (Journal of Laws of 2013, item 21). Act of 13 June 2013 on the management of packaging and packaging waste, Journal of Laws 2013, item 888). Government statement of September 24, 2002 - European Agreement on the International Carriage of Dangerous Goods by Road (ADR) (Journal of Laws No. 194, item 1629 and Journal of Laws of 2003, No. 207, item 2013 and 2014).

European Union

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

Authorisations and/or restrictions on use:

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

DIRECTIVE (EU) 2021/1187 on the marketing and use of explosives precursors

Not applicable

Persistent Organic Pollutants

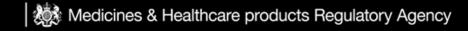
Not applicable

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	Contact supplier for inventory compliance status
EINECS/ELINCS	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
PICCS	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 and Evaluated Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report A Chemical Safety Assessment is not required for this substance

SECTION 16: Other information

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

Full text of H-Statements referred to under section 3

H302 - Harmful if swallowed H361d - Suspected of damaging the unborn child

H400 - Very toxic to aquatic life

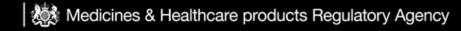
Legend

SVHC: Substances of Very High Concern for Authorisation:

Legend Section 8: Exposure controls/personal protection

TWA Ceiling	TWA (time-weighted average) Maximum limit value	STEL *	STEL (Short Term Exposure Limit) Skin designation
Classification	n procedure		
Classification	according to Regulation (EC) No. 1272/200	8 [CLP] Metho	nd Lised

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





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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	

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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