

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-Sep-2021 Revision Number 1

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

1.1. Product identifier

Product Code(s) LGCFOR3370.00

Product Name Cinacalcet Hydrochloride

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)** 620-490-5

**CAS No.** 346482-34-3

Pure substance/mixture Substance

Formula C22 H22 F3 N.HCl

Molecular weight 393.88

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**

LGC Limited Queens Road Teddington Middlesex TW11 0LY UNITED KINGDOM :+44 (0) 20 8943 7000 Fax :+44 (0) 20 8943 2767 eMail : gb@lgcstandards.com

Web: www.lgcstandards.com

For further information, please contact

E-mail address sds-request@lgcgroup.com

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### 1.4. Emergency telephone number

Emergency Telephone For Hazardous Materials or Dangerous Goods Incident

Spill, Leak, Fire Exposure, or Accident

Call CHEMTREC:

USA & Canada 1-800-424-9300 Rest of the world +1 703-741-3877

Emergency Telephone - §45 - (EC)1272/2008			
Europe	112		
Austria	No information available	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]

9	
Acute toxicity - Oral	Category 4 - (H302)
Serious eye damage/eye irritation	Category 1 - (H318)
Skin sensitisation	Category 1 - (H317)
Specific target organ toxicity — single exposure	Category 3 - (H336)

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Category 3 Narcotic effects		
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

#### 620-490-5

Contains Cinacalcet Hydrochloride



Signal word Danger

#### **Hazard statements**

H302 - Harmful if swallowed

H317 - May cause an allergic skin reaction

H318 - Causes serious eye damage

H336 - May cause drowsiness or dizziness

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)

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

P273 - Avoid release to the environment

P280 - Wear protective gloves and eye/face protection

P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

P310 - Immediately call a POISON CENTER or doctor

P391 - Collect spillage

#### 2.3. Other hazards

No information available.

Endocrine Disruptor Information This pr	uct 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	
Cinacalcet Hydrochloride	-	-	

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## **SECTION 3: Composition/information on ingredients**

#### 3.1 Substances

	Chemical name	Weight-%	REACH registration	,	Classification according	•	M-Factor	M-Factor
١			number	Index No)	to Regulation (EC) No.	concentration		(long-term)
I					1272/2008 [CLP]	limit (SCL)		
	Cinacalcet	100	-	620-490-5	Acute Tox. 4 (H302)			
	Hydrochloride				Eye Dam. 1 (H318)			
	364782-34-3				Skin Sens. 1 (H317)			
					STOT SE 3 (H336)			
					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. Immediate medical attention is

required.

**Inhalation** Remove to fresh air. Get medical attention immediately if symptoms occur. IF exposed or

concerned: Get medical advice/attention.

**Eye contact** Get immediate medical attention. Rinse immediately with plenty of water, also under the

eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue

rinsing. Keep eye wide open while rinsing. Do not rub affected area.

**Skin contact** Wash off immediately with soap and plenty of water for at least 15 minutes. May cause an

allergic skin reaction. 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.

Self-protection of the first aider Avoid contact with skin, eyes or clothing. Wear personal protective clothing (see section 8).

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

Symptoms Burning sensation. Itching. Rashes. Hives. Inhalation of high vapour concentrations may

cause symptoms like headache, dizziness, tiredness, nausea and vomiting.

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

**Note to doctors**May cause sensitisation in susceptible persons. Treat 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

Product is or contains a sensitiser. May cause sensitisation by skin contact.

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 Avoid contact with skin, eyes or clothing. Use personal protective equipment as required.

Ensure adequate ventilation. Evacuate personnel to safe areas. Keep people away from

and upwind of spill/leak.

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

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For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

**Environmental precautions** Prevent further leakage or spillage if safe to do so.

6.3. Methods and material for containment and cleaning up

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

Take up mechanically, placing in appropriate containers for disposal. Methods for cleaning up

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

Handle in accordance with good industrial hygiene and safety practice. Avoid contact with Advice on safe handling

skin, eves or clothing. Do not eat, drink or smoke when using this product. Ensure adequate ventilation. In case of insufficient ventilation, wear suitable respiratory equipment. Take off

contaminated clothing and wash it before reuse. Avoid breathing vapours or mists.

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 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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## 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

No information available. No information available.

(PNEC)

8.2. Exposure controls

Personal protective equipment

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

safety goggles.

Hand protection Wear protective butyl rubber gloves. 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.

**Skin and body protection**Wear suitable protective clothing.

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

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9.1. Information on basic physical and chemical properties

**Physical state** Solid **Appearance** Solid

Colour white to beige

Odour No information available. No information available **Odour threshold** 

Remarks • Method Property Values

No data available Melting point / freezing point None known Initial boiling point and boiling rangeNo data available None known **Flammability** No data available None known Flammability Limit in Air None known

Upper flammability or explosive No data available

Lower flammability or explosive No data available

limits

Flash point No data available None known No data available **Autoignition temperature** None known 175 - 177 °C **Decomposition temperature** None known No data available None known pН

pH (as aqueous solution) No data available No information available

Kinematic viscosity No data available None known No data available Dynamic viscosity None known Water solubility No data available None known

Solubility(ies) Chloroform, Acetonitrile, Methanol,

slightly soluble

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

No data available **Bulk density** No data available **Liquid Density** 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 393.88

Molecular formula C22 H22 F3 N.HCI

9.2.1. Information with regards to physical hazard classes

Not applicable 175 - 177 °C 175 - 177 °C

9.2.2. Other safety characteristics

No information available

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## 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** Strong acids. Strong bases. Strong oxidising agents.

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. May cause drowsiness or

dizziness.

**Eye contact** Specific test data for the substance or mixture is not available. Causes serious eye damage.

May cause irreversible damage to eyes.

**Skin contact** Specific test data for the substance or mixture is not available. May cause irritation. May

cause sensitisation by skin contact. Repeated or prolonged skin contact may cause allergic

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reactions with susceptible persons. (based on components).

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

gastrointestinal irritation, nausea, vomiting and diarrhoea. Harmful if swallowed. (based on

components).

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms Redness. Burning. May cause blindness. Itching. Rashes. Hives. Inhalation of high vapour

concentrations may cause symptoms like headache, dizziness, tiredness, nausea and

vomiting.

Numerical measures of toxicity

No information available

**Acute toxicity** 

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

**Skin corrosion/irritation** May cause skin irritation.

Serious eye damage/eye irritation Classification based on data available for ingredients. Causes burns. Causes serious eye

damage.

**Respiratory or skin sensitisation** May cause an allergic skin reaction.

**Germ cell mutagenicity** No information available.

**Carcinogenicity** No information available.

**Reproductive toxicity**No information available.

**STOT - single exposure** May cause drowsiness or dizziness.

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**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

**Ecotoxicity** Very toxic to aquatic life with long lasting effects.

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.

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#### 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.

Do not reuse empty containers. Contaminated packaging

### **SECTION 14: Transport information**

14.1 UN number or ID number

14.2 UN proper shipping name Environmentally hazardous substances, solid, n.o.s. (Cinacalcet Hydrochloride)

14.3 Transport hazard class(es)

14.4 Packing group

Description UN3077, Environmentally hazardous substances, solid, n.o.s. (Cinacalcet Hydrochloride),

> 9, III Yes

14.5 Environmental hazards

14.6 Special precautions for user

**Special Provisions** 

**ERG Code** 

A97, A158, A179, A197, A215

IMDG

14.1 UN number or ID number UN3077

14.2 UN proper shipping name Environmentally hazardous substances, solid, n.o.s. (Cinacalcet Hydrochloride)

14.3 Transport hazard class(es)

14.4 Packing group

Description UN3077, Environmentally hazardous substances, solid, n.o.s. (Cinacalcet Hydrochloride),

9, III, Marine pollutant

14.5 Marine pollutant

**Environmental hazards** Yes

14.6 Special precautions for user

274, 335, 966, 967, 969 **Special Provisions** 

F-A, S-F No information available EmS-No. No information available

Ρ

14.7 Maritime transport in bulk according to IMO instruments

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#### LGCFOR3370.00 - Cinacalcet Hydrochloride

RID

14.1 UN number or ID number UN3077

**14.2 UN proper shipping name** Environmentally hazardous substances, solid, n.o.s. (Cinacalcet Hydrochloride)

14.3 Transport hazard class(es)914.4 Packing group

**Description** UN3077, Environmentally hazardous substances, solid, n.o.s. (Cinacalcet Hydrochloride),

9, III Yes

14.5 Environmental hazards

14.6 Special precautions for user

**Special Provisions** 274, 335, 375, 601

Classification code M7

ADR

14.1 UN number or ID number UN3077

**14.2 UN proper shipping name** Environmentally hazardous substances, solid, n.o.s. (Cinacalcet Hydrochloride)

14.3 Transport hazard class(es)914.4 Packing group

**Description**UN3077, Environmentally hazardous substances, solid, n.o.s. (Cinacalcet Hydrochloride),

9, III, (-) Yes

14.5 Environmental hazards

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) 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

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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, 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

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**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
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
KECI
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:

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

H317 - May cause an allergic skin reaction

H318 - Causes serious eye damage

H336 - May cause drowsiness or dizziness

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

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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 Sk\* 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			
Reproductive toxicity	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)

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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

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. LGC makes no warranties or representations as to the accuracy and completeness of the information contained herein, shall not be held responsible 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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