

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

Revision date 26-Mar-2024 Revision Number 1

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

1.1. Product identifier

Product Code(s) TRC-F376340-100MG

Product Name (3S)-9-Fluoro-2,3-dihydro-3-methyl-10-(4-nitroso-1-piperazinyl)-7-oxo-7H-pyrido[1,2,3-de]-1

,4-benzoxazine-6-carboxylic Acid

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) -

CAS No. 1152314-62-9

Chemical name N-Desmethyl-N-nitrosolevofloxacine

Pure substance/mixture Substance

Formula C17 H17 F N4 O5

Molecular weight 376.30

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

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E-mail address sds-request@lgcgroup.com

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 +1 703-741-5970

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]

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Acute toxicity - Oral	Category 4 - (H302)
Serious eye damage/eye irritation	Category 2 - (H319)
Respiratory sensitisation	Category 1 - (H334)
Skin sensitisation	Category 1 - (H317)
Reproductive toxicity	Category 2 - (H361)
Specific target organ toxicity — single exposure	Category 2

2.2. Label elements

Contains N-Desmethyl-N-nitrosolevofloxacine





Signal word Danger

Hazard statements

- H302 Harmful if swallowed
- H317 May cause an allergic skin reaction
- H319 Causes serious eye irritation
- H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled
- H361 Suspected of damaging fertility or the unborn child
- H371 May cause damage to organs

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

- P260 Do not breathe dust/fume/gas/mist/vapours/spray
- P264 Wash face, hands and any exposed skin thoroughly after handling
- P280 Wear protective gloves/protective clothing/eye protection/face protection
- P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing
- 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.

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

product access that continues and the continues are	
Chemical name	EU - REACH (1907/2006) - Article 59(1) EU - REACH (1907/2006) - Endocrine

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	- Candidate List of Substances of Very High Concern (SVHC) for Authorisation	Disruptor Assessment List of Substances
N-Desmethyl-N-nitrosolevofloxacine	-	-

SECTION 3: Composition/information on ingredients

3.1 Substances

Chemical name	Weight-%	REACH registration	EC No (EU	Classification according	Specific	M-Factor	M-Factor
		number	Index No)	to Regulation (EC) No.	concentration		(long-term)
				1272/2008 [CLP]	limit (SCL)		
N-Desmethyl-N-nitro	100	=	-	Acute Tox. 4 (H302)			
solevofloxacine				Eye Irrit. 2 (H319)			
1152314-62-9				Resp. Sens. 1 (H334)			
				Skin Sens. 1 (H317)			
				Repr. 2 (H361)			
				STOT SE 2 (H371)			

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. May cause allergic respiratory reaction. If breathing has stopped, give

artificial respiration. Get medical attention immediately. Avoid direct contact with skin. Use

barrier to give mouth-to-mouth resuscitation. Get immediate medical attention.

Eye contact 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. Get medical attention if irritation develops and

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persists. If symptoms persist, call a doctor.

Skin contact Wash with soap and water. May cause an allergic skin reaction. Wash off immediately with

plenty of water for at least 15 minutes. If symptoms persist, call a doctor.

Ingestion Do NOT induce vomiting. Rinse mouth. Never give anything by mouth to an unconscious

person. May produce an allergic reaction. Get immediate medical attention.

Self-protection of the first aider

Avoid contact with skin, eyes or clothing. Ensure that medical personnel are aware of the

material(s) involved, take precautions to protect themselves and prevent spread of contamination. Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation. Use personal protective equipment as required. See section 8 for more

information.

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

Symptoms May cause redness and tearing of the eyes. Burning sensation. May cause allergy or

asthma symptoms or breathing difficulties if inhaled. Coughing and/ or wheezing. Itching.

Rashes. Hives.

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 inhalation and skin contact.

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.

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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.

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.

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.

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. Ensure adequate ventilation. Provide extract ventilation to points where emissions occur. In case of

insufficient ventilation, wear suitable respiratory equipment. Remove contaminated clothing

and shoes. Take off contaminated clothing and wash it before reuse.

General hygiene considerations Remove and wash contaminated clothing and gloves, including the inside, before re-use.

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

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before breaks and after work. Wear suitable gloves and eye/face protection.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach

of children. Store locked up. 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.

8.2. Exposure controls

Personal protective equipment

Eye/face protection If splashes are likely to occur, wear safety glasses with side-shields. Avoid contact with

eyes. Wear safety glasses with side shields (or goggles).

Hand protection Wear suitable gloves. 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

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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 Remove and wash contaminated clothing and gloves, including the inside, before re-use.

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 and chemical properties

Physical state Solid Appearance Solid

Colouroff-white to light yellowOdourNo information available.Odour thresholdNo information available

Property Values Remarks • Method

Melting point / freezing pointNo data availableNone 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

limits

Flash pointNo data availableNone knownAutoignition temperatureNo data availableNone knownDecomposition temperature> 230 °CNone knownpHNo data availableNone known

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

Kinematic viscosityNo data availableNone knownDynamic viscosityNo data availableNone knownWater solubilityNo data availableNone knownSolubility(ies)DMSO, slightly solubleNone known

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None known

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

Liquid Density No data available No data available

Relative vapour density

Particle characteristics Particle Size No information available **Particle Size Distribution** No information available

9.2. Other information

Molecular weight 376.30

Molecular formula C17 H17 F N4 O5

9.2.1. Information with regards to physical hazard classes Not applicable > 230 °C > 230 °C

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

Stable under normal conditions. Stability

Explosion data

Sensitivity to mechanical impact None. Sensitivity to static discharge

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

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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. May cause sensitisation in

susceptible persons. (based on components).

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

(based on components). May cause redness, itching, and pain.

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

Prolonged contact may cause redness and irritation. Repeated or prolonged skin contact may cause allergic reactions with susceptible persons. (based on components). May cause

sensitisation by skin contact.

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). May cause additional affects as listed under "Inhalation".

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms May cause redness and tearing of the eyes. Symptoms of allergic reaction may include

rash, itching, swelling, trouble breathing, tingling of the hands and feet, dizziness, lightheadedness, chest pain, muscle pain, or flushing. Coughing and/ or wheezing. Itching.

lightneadedness, chest pain, muscle pain, or hushing. Coughing and/ or wheezing. Itching

Rashes. Hives.

Numerical measures of toxicity

Acute toxicity

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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 serious eye irritation.

Respiratory or skin sensitisation May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an

allergic skin reaction.

Germ cell mutagenicity No information available.

Carcinogenicity No information available.

Reproductive toxicity Suspected of damaging fertility or the unborn child. Contains a known or suspected

reproductive toxin. Classification based on data available for ingredients.

STOT - single exposure May cause damage to organs if swallowed. Based on the classification criteria of the

Globally Harmonized System as adopted in the country or region with which this safety data sheet complies, this product has been determined to cause systemic target organ toxicity

from acute exposure, (STOT SE).

STOT - repeated exposureNo information available.

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

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Other adverse effects No information available.

SECTION 12: Ecological information

12.1. Toxicity

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

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 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).

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.

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Contaminated packaging Do not reuse empty containers.

SECTION 14: Transport information

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_	1	

14.1 UN number or ID number
 14.2 UN proper shipping name
 14.3 Transport hazard class(es)
 14.4 Packing group
 14.5 Environmental hazards
 Not regulated Not regulated Not applicable

14.6 Special precautions for user

Special Provisions None

IMDG

14.1UN number or ID numberNot regulated14.2UN proper shipping nameNot regulated14.3Transport hazard class(es)Not regulated14.4Packing groupNot regulated14.5Marine pollutantNot applicable

14.6 Special precautions for user

Special Provisions
None No information available
No information available

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
14.5 Environmental hazards
Not regulated
Not regulated
Not regulated
Not applicable

14.6 Special precautions for user

Special Provisions None

ADR

14.1UN number or ID numberNot regulated14.2UN proper shipping nameNot regulated14.3Transport hazard class(es)Not regulated14.4Packing groupNot regulated14.5Environmental hazardsNot applicable

14.6 Special precautions for user

Special Provisions None

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SECTION 15: Regulatory information

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

Water hazard class (WGK) obviously hazardous to water (WGK 2)

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, 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

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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 precursorsNot applicable

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009 Not applicable

International Inventories

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

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

at 40 CFR 720.36. It is the end-user's responsibility to understand and follow the requirements that apply to its use of this product.

DSL/NDSL
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
PICCS
Contact supplier for inventory compliance status
Contact supplier for inventory compliance status
AllC
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

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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

H319 - Causes serious eye irritation

H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

H361 - Suspected of damaging fertility or the unborn child

H371 - May cause damage to organs

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 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
STOT - single exposure	Calculation method
STOT - repeated exposure	Calculation method
Acute aquatic toxicity	Calculation method
Chronic aquatic toxicity	Calculation method
Aspiration hazard	Calculation method

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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 26-Mar-2024 Revision Number 1

TRC-F376340-100MG -

(3S)-9-Fluoro-2,3-dihydro-3-methyl-10-(4-nitroso-1-piperazinyl)-7-oxo-7H-pyrido[1,2,3-de]-1,4-benzoxazine-6-c arboxylic Acid

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

Revision date 26-Mar-2024

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

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End of Safety Data Sheet

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