



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 19-Sep-2023

Revision Number 1.2

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

1.1. Product identifier

Product Name Exact Diagnostics RP Negative Run Control

Catalogue Number(s) RPNEG

Nanoforms Not applicable

Pure substance/mixture Mixture

Contains 5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended use In vitro diagnostic

Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

Corporate Headquarters

Bio-Rad Laboratories Inc.
1000 Alfred Nobel Drive
Hercules, CA 94547
USA

Manufacturer

Exact Diagnostics
100 South Jones Street, Suite 100,
Fort Worth, Texas 76104
USA

Legal Entity / Contact Address

Bio-Rad Laboratories Ltd
The Junction
Station Road
Watford, WD17 1ET
UK

Bio-Rad Laboratories Pvt. Ltd.
Bio-Rad House
86-87, Udyog Vihar Phase IV Gurgaon
122005
Haryana India

Bio-Rad Laboratories (Pty) Ltd.
34 Bolton Road
Parkwood, Johannesburg 2193
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For further information, please contact

Technical Service

00800 00246 723
Ireland: Techsupport.UK@bio-rad.com
India: support.india@bio-rad.com
South Africa: cdg_techsupport_eemea@bio-rad.com

1.4. Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC Ireland: 353-19014670
CHEMTREC India: 000-800-100-7141
CHEMTREC South Africa: 0-800-983-611

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

Skin sensitisation

Category 1A - (H317)

2.2. Label elements

Contains 5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone

**Signal word**

Warning

Hazard statements

H317 - May cause an allergic skin reaction

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

P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention

P302 + P352 - IF ON SKIN: Wash with plenty of soap and water

P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable

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

2.3. Other hazards**SECTION 3: Composition/information on ingredients****3.1 Substances**

Not applicable

3.2 Mixtures

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Trade secret	10 - 20	No data available	.?	No data available	-	-	-
Trade secret	0.3 - 0.99	No data available	.?	No data available	-	-	-
Trade secret	0.01 - 0.099	No data available	.?	No data available	-	-	-
Trade secret	0.01 - 0.099	No data available	.?	Eye Irrit. 2 (H319)	-	-	-
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone 55965-84-9	0.001 - 0.01	No data available	(613-167-00-5)	Acute Tox. 3 (H301) Acute Tox. 3 (H311) Acute Tox. 3 (H331) Skin Corr. 1B (H314) Eye Dam. 1 (H318) Skin Sens. 1A (H317) (EUH071) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	Eye Irrit. 2 :: 0.06%≤C<0.6% Skin Corr. 1C :: C≥0.6% Skin Irrit. 2 :: 0.06%≤C<0.6% Skin Sens. 1A :: C≥0.0015% Eye Dam. 1 :: C≥0.6%	100	100

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	Dermal LD50 mg/kg	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapour - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Trade secret	29700	No data available	No data available	No data available	No data available
Trade secret	3000	10000	Inhalation LC50 Rat >42 mg/L 1 h (no deaths occurred, aerosol, Source: ECHA_API)	>42	Inhalation LC50 Rat >42 mg/L 1 h (no deaths occurred, aerosol, Source: ECHA_API)
Trade secret	4220	No data available	No data available	No data available	No data available
Trade secret	1000	5000	No data available	No data available	No data available
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone 55965-84-9	53	87.12	No data available	No data available	No data available

This product does not contain candidate substances of very high concern at a concentration $\geq 0.1\%$ (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 with soap and water. May cause an allergic skin reaction. 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 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

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
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Large Fire	CAUTION: Use of water spray when fighting fire may be inefficient.
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Unsuitable extinguishing media	Do not scatter spilled material with high pressure water streams.
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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.
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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. Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak.
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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.
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6.3. Methods and material for containment and cleaning up

Methods for containment	Prevent further leakage or spillage if safe to do so.
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Methods for cleaning up	Take up mechanically, placing in appropriate containers for disposal.
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Prevention of secondary hazards	Clean contaminated objects and areas thoroughly observing environmental regulations.
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6.4. Reference to other sections

Reference to other sections	See section 8 for more information. See section 13 for more information.
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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. Ensure adequate ventilation. In case of insufficient ventilation, wear suitable respiratory equipment. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash it before reuse.
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General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.
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7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions	Keep containers tightly closed in a dry, cool and well-ventilated place. Store according to product and label instructions.
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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

Chemical name	European Union	Austria	Belgium	Bulgaria	Croatia
Trade secret	-	-	TWA: 10 mg/m ³	TWA: 10.0 mg/m ³	TWA: 10 mg/m ³ STEL: 20 mg/m ³
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone 55965-84-9	-	TWA: 0.05 mg/m ³ Sh+	-	-	-
Chemical name	Cyprus	Czech Republic	Denmark	Estonia	Finland
Trade secret	-	-	-	TWA: 10 mg/m ³	-
Trade secret	-	TWA: 5 mg/m ³ Ceiling: 10 mg/m ³	-	-	-
Trade secret	-	TWA: 5 mg/m ³ Ceiling: 4 mg/m ³	-	-	-
Chemical name	France	Germany TRGS	Germany DFG	Greece	Hungary
Trade secret	TWA: 10 mg/m ³	-	-	-	-
Chemical name	Ireland	Italy MDLPS	Italy AIDII	Latvia	Lithuania
Trade secret	TWA: 10 mg/m ³ STEL: 20 mg/m ³	-	TWA: 10 mg/m ³	TWA: 5 mg/m ³	TWA: 10 mg/m ³
Trade secret	-	-	-	TWA: 5 mg/m ³	TWA: 5 mg/m ³
Trade secret	-	-	-	TWA: 5 mg/m ³	-
Trade secret	-	-	-	TWA: 2 mg/m ³	-
Chemical name	Portugal	Romania	Slovakia	Slovenia	Spain
Trade secret	TWA: 10 mg/m ³	-	-	-	TWA: 10 mg/m ³
Chemical name	Sweden		Switzerland		United Kingdom
Trade secret	-		-		TWA: 10 mg/m ³ STEL: 20 mg/m ³
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone 55965-84-9	-		S+ TWA: 0.2 mg/m ³ STEL: 0.4 mg/m ³		-

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 (PNEC)

8.2. Exposure controls

Personal protective equipment

Eye/face protection	Wear safety glasses with side shields (or goggles).
Hand protection	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	Handle in accordance with good industrial hygiene and safety practice.
Environmental exposure controls	No information available.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Liquid
Colour	clear
Odour	No information available.
Odour threshold	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
Melting point / freezing point	No data available	None known
Boiling point / boiling range	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Flash point	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature		None known
pH	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	
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.

10.5. Incompatible materials

Incompatible materials None known based on information supplied.

10.6. Hazardous decomposition products

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 May cause sensitisation by skin contact. Specific test data for the substance or mixture is not available. Repeated or prolonged skin contact may cause allergic reactions with susceptible persons. (based on components).

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

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms Itching. Rashes. Hives.

Acute toxicity

Numerical measures of toxicity

The following values are calculated based on chapter 3.1 of the GHS document

ATEmix (oral) 62,305.30 mg/kg

ATEmix (dermal) 62,305.30 mg/kg

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Trade secret	= 29700 mg/kg (Rat)	-	-
Trade secret	= 3 g/kg (Rat)	> 10000 mg/kg (Rabbit)	> 42 mg/L (Rat) 1 h

Trade secret	= 4220 mg/kg (Rat)	-	-
Trade secret	= 1000 mg/kg (Rat)	> 5000 mg/kg (Rabbit)	-
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone	= 53 mg/kg (Rat)	= 87.12 mg/kg (Rabbit)	-

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

Skin corrosion/irritation	No information available.
Serious eye damage/eye irritation	No information available.
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	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 properties**

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

11.2.2. Other information

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.

Unknown aquatic toxicity Contains 1E-05 % of components with unknown hazards to the aquatic environment.

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Trade secret	-	LC50: 5560 - 6080mg/L (96h, <i>Lepomis macrochirus</i>) LC50: =12946mg/L (96h, <i>Lepomis macrochirus</i>)	-	EC50: =1000mg/L (48h, <i>Daphnia magna</i>) EC50: 340.7 - 469.2mg/L (48h, <i>Daphnia magna</i>)

		LC50: 6020 - 7070mg/L (96h, Pimephales promelas) LC50: =7050mg/L (96h, Pimephales promelas) LC50: 6420 - 6700mg/L (96h, Pimephales promelas) LC50: 4747 - 7824mg/L (96h, Oncorhynchus mykiss)		
Trade secret	-	LC50: 8250 - 9000mg/L (96h, Lepomis macrochirus)	-	EC50: =2350mg/L (48h, Daphnia magna)
Trade secret	-	LC50: =10650mg/L (96h, Lepomis macrochirus)	-	LC50: 2280000 - 3948000µg/L (48h, Daphnia magna)

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential**Bioaccumulation****Component Information**

Chemical name	Partition coefficient
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone	0.7

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment**PBT and vPvB assessment**

Chemical name	PBT and vPvB assessment
Trade secret	The substance is not PBT / vPvB
Trade secret	The substance is not PBT / vPvB
Trade secret	The substance is not PBT / vPvB
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone	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

IATA

14.1 UN number or ID number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazards	Not applicable
14.6 Special Precautions for Users	
Special Provisions	None

IMDG

14.1 UN number or ID number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazards	Not applicable
14.6 Special Precautions for Users	
Special Provisions	None
14.7 Maritime transport in bulk according to IMO instruments	No information available

RID

14.1 UN number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazards	Not applicable
14.6 Special Precautions for Users	
Special Provisions	None

ADR

14.1 UN number or ID number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazards	Not applicable
14.6 Special Precautions for Users	
Special Provisions	None

SECTION 15: Regulatory information

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

National regulations

France

Occupational Illnesses (R-463-3, France)

Chemical name	French RG number	Title
Trade secret	RG 78	-

Germany

Water hazard class (WGK) slightly hazardous to water (WGK 1)

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 contains one or more substance(s) subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Chemical name	Restricted substance per REACH Annex XVII	Substance subject to authorisation per REACH Annex XIV
Trade secret -	75.	-
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone - 55965-84-9	75.	-

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

EU - Plant Protection Products (1107/2009/EC)

Chemical name	EU - Plant Protection Products (1107/2009/EC)
Trade secret -	Plant protection agent
Trade secret -	Plant protection agent
Trade secret -	Plant protection agent

Biocidal Products Regulation (EU) No 528/2012 (BPR)

Chemical name	Biocidal Products Regulation (EU) No 528/2012 (BPR)
Trade secret -	Product-type 1: Human hygiene
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone - 55965-84-9	Product-type 2: Disinfectants and algaecides not intended for direct application to humans or animals Product-type 4: Food and feed area Product-type 6: Preservatives for products during storage Product-type 11: Preservatives for liquid-cooling and processing systems Product-type 12: Slimicides Product-type 13: Working or cutting fluid preservatives

International Inventories

Contact supplier for inventory compliance status

15.2. Chemical safety assessment**Chemical Safety Report**

No information available

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**

EUH071 - Corrosive to the respiratory tract

H301 - Toxic if swallowed

H311 - Toxic in contact with skin

H314 - Causes severe skin burns and eye damage

H317 - May cause an allergic skin reaction

H318 - Causes serious eye damage

H319 - Causes serious eye irritation

H331 - Toxic if inhaled

H400 - Very toxic to aquatic life

H410 - Very toxic to aquatic life with long lasting effects

Legend

SVHC: Substances of Very High Concern for Authorisation:

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA TWA (time-weighted average) STEL STEL (Short Term Exposure Limit)
 Ceiling Maximum limit value * Skin designation

Classification procedure	
Classification according to Regulation (EC) No. 1272/2008 [CLP]	Method Used
Acute oral toxicity	Calculation method
Acute dermal toxicity	Calculation method
Acute inhalation toxicity - gas	Calculation method
Acute inhalation toxicity - vapour	Calculation method
Acute inhalation toxicity - dust/mist	Calculation method
Skin corrosion/irritation	Calculation method
Serious eye damage/eye irritation	Calculation method
Respiratory sensitisation	Calculation method
Skin sensitisation	Calculation method
Mutagenicity	Calculation method
Carcinogenicity	Calculation method
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)
 European Chemicals Agency (ECHA) Committee for Risk Assessment (ECHA_RAC)
 European Chemicals Agency (ECHA) (ECHA_API)
 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)
 National Institute of Technology and Evaluation (NITE)
 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 Note Significant changes throughout SDS. Review all sections

Revision date 19-Sep-2023

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

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet