

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 16-Mar-2023 Revision Number 3.2

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

1.1. Product identifier

Product Name BioPlex 2200 Syphilis Total & RPR Calibrator Set

Catalogue Number(s) 12000651

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

Restricted to professional users

Use according to package label instructions

Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

Corporate HeadquartersManufacturerBio-Rad Laboratories Inc.Bio-Rad Laboratories1000 Alfred Nobel Drive6565-185th Ave NEHercules, CA 94547Redmond, WA 98052

USA USA

Legal Entity / Contact Address

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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

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Skin sensitisation	Category 1A - (H317)
Chronic aquatic toxicity	Category 3 - (H412)

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

H412 - Harmful to aquatic life with long lasting effects

EUH210 - Safety data sheet available on request

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

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

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

P273 - Avoid release to the environment

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

2.3. Other hazards

Harmful to aquatic life.

Contains human source material and / or potentially infectious components

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Component	Description
Calibrator	Syphilis Total & RPR Calibrators: 5 x 0.5 mL vials. The calibrators are provided in a human serum matrix
	made from defibrinated plasma with added known analyte concentrations of Treponema pallidum and/ or
	reagin antibodies derived from human disease state plasma, and added preservatives including ≤ 0.3%
	ProClin 300, < 0.1% sodium azide and ≤ 0.1% sodium benzoate

Chemical name	Weight-%	REACH registration number	,	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Sodium benzoate 532-32-1	0.1 - 0.299	No data available	208-534-8	No data available	-	-	-
Sodium azide 26628-22-8	0.01 - 0.099	No data available	247-852-1	Acute Tox. 2 (H300) Acute Tox. 1 (H310) (EUH032) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	-	-	-
5-Chloro-2-methyl-3 (2H)-isothiazolone, mixture with	0.001 - 0.01	No data available	-	Acute Tox. 3 (H301) Acute Tox. 3 (H311) Acute Tox. 3 (H331)	Eye Irrit. 2 :: 0.06%<=C<0.6 %	100	100

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2-methyl-3(2H)-isoth	Skin Corr. 1B (H314) Skin Corr. 1C ::
iazolone	Eve Dam. 1 (H318) C>=0.6%
55965-84-9	Skin Sens. 1A (H317) Skin Irrit. 2 ::
	(EUH071) 0.06%<=C<0.6
	Aquatic Acute 1 (H400) %
	Aquatic Chronic 1 Skin Sens. 1A
	(H410) :: C>=0.0015%
	Eye Dam. 1 ::
	C>=0.6%

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	Inhalation LC50 - 4	Inhalation LC50 - 4	Inhalation LC50 - 4
		mg/kg	hour - dust/mist - mg/L	hour - vapour - mg/L	hour - gas - ppm
Sodium benzoate 532-32-1	4070	No data available	No data available	No data available	No data available
Sodium azide 26628-22-8	27	20	No data available	No data available	No data available
5-Chloro-2-methyl-3(2H)-i sothiazolone, mixture with 2-methyl-3(2H)-isothiazol one 55965-84-9		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 >=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 contactCall a doctor. Rinse immediately with plenty of water, also under the eyelids, for at least 15

minutes.

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 Call a doctor. Contains human source material and / or potentially infectious components.

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. Contains human

source material and / or potentially infectious components.

SECTION 5: Firefighting measures

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5.1. Extinguishing media

Suitable Extinguishing Media Use extinguishing measures that are appropriate to local circumstances and the

surrounding environment.

CAUTION: Use of water spray when fighting fire may be inefficient. Large Fire

Do not scatter spilled material with high pressure water streams. Unsuitable extinguishing media

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

Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Use personal Personal precautions

protective equipment as required. Evacuate personnel to safe areas. Keep people away

from and upwind of spill/leak.

Use personal protection recommended in Section 8. For emergency responders

6.2. Environmental precautions

See Section 12 for additional Ecological Information. **Environmental precautions**

6.3. Methods and material for containment and cleaning up

Methods for containment Do not allow into any sewer, on the ground or into any body of water.

Clean contaminated surface thoroughly. Use:. Disinfectant. 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, 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.

General hygiene considerations Follow universal and standard precautions for handling potentially infectious materials.

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		Ilgaria	Croatia
Sodium azide 26628-22-8	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ *	TWA: 0.1 mg/m³ STEL 0.3 mg/m³ H*	*	TWA: (0.3 mg/m ³ 0.1 mg/m ³ K*	TWA: 0.1 mg/m³ STEL: 0.3 mg/m³ *
5-Chloro-2-methyl-3(2H)-i sothiazolone, mixture with 2-methyl-3(2H)-isothiazol one 55965-84-9	-	TWA: 0.05 mg/m³ Skin sensitizer	-		-	-
Chemical name	Cyprus	Czech Republic	Denmark		stonia	Finland
Sodium azide 26628-22-8	* STEL: 0.3 mg/m³ TWA: 0.1 mg/m³	TWA: 0.1 mg/m³ Ceiling: 0.3 mg/m³ *	TWA: 0.1 mg/m³ H*	STEL:	0.1 mg/m ³ 0.3 mg/m ³ A*	TWA: 0.1 mg/m³ STEL: 0.3 mg/m³ iho*
Chemical name	France	Germany TRGS	Germany DFG	Gı	reece	Hungary
Sodium benzoate 532-32-1	-	TWA: 10 mg/m ³ H*	TWA: 10 mg/m ³ Peak: 20 mg/m ³		-	-
Sodium azide 26628-22-8	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ *	TWA: 0.2 mg/m ³	TWA: 0.2 mg/m ³ Peak: 0.4 mg/m ³	TWA: (0.1 ppm 0.3 mg/m ³ : 0.1 ppm 0.3 mg/m ³	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³
Chemical name	Ireland	Italy MDLPS	Italy AIDII		atvia	Lithuania
Sodium azide 26628-22-8	TWA: 0.1 mg/m³ STEL: 0.3 mg/m³ Sk*	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ pelle*	Ceiling: 0.29 mg/m ³ Ceiling: 0.11 ppm		0.1 mg/m ³ 0.3 mg/m ³	* TWA: 0.1 mg/m³ STEL: 0.3 mg/m³
Chemical name	Luxembourg	Malta	Netherlands	No	orway	Poland
Sodium azide 26628-22-8	* STEL: 0.3 mg/m³ TWA: 0.1 mg/m³	* STEL: 0.3 mg/m ³ TWA: 0.1 mg/m ³	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ H*		0.1 mg/m ³ 0.3 mg/m ³	STEL: 0.3 mg/m ³ TWA: 0.1 mg/m ³ *
Chemical name	Portugal	Romania	Slovakia		ovenia	Spain
Sodium benzoate 532-32-1	-	-	-	STEL:	10 mg/m³ 20 mg/m³ *	-
Sodium azide 26628-22-8	TWA: 0.1 mg/m³ STEL: 0.3 mg/m³ Ceiling: 0.29 mg/m³ Ceiling: 0.11 ppm P*	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ *	TWA: 0.1 mg/m ³ * Ceiling: 0.3 mg/m ³		0.1 mg/m ³ 0.3 mg/m ³ *	TWA: 0.1 mg/m³ STEL: 0.3 mg/m³ vía dérmica*
Chemical name	Sı	weden	Switzerland	Unit		ted Kingdom
Sodium benzoate 532-32-1		-	TWA: 0.2 ppm TWA: 1 mg/m³ TWA: 10 mg/m³ STEL: 0.8 ppm STEL: 4 mg/m³ STEL: 20 mg/m H*	3 3 1 3		-
Sodium azide 26628-22-8		0.1 mg/m ³ (GV: 0.3 mg/m ³	TWA: 0.2 mg/m STEL: 0.4 mg/m			EL: 0.3 mg/m ³

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5-Chloro-2-methyl-3(2H)-isothia	-	TWA: 0.2 mg/m ³	-
zolone, mixture with		STEL: 0.4 mg/m ³	
2-methyl-3(2H)-isothiazolone			
55965-84-9			

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.

8.2. Exposure controls

Personal protective equipment

Eye/face protection Wear safety glasses with side shields (or goggles).

Hand protection Wear suitable gloves.

Wear suitable protective clothing. Skin and body protection

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.

Follow universal and standard precautions for handling potentially infectious materials. **General hygiene considerations**

Environmental exposure controls No information available.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

No information available Physical state

Appearance Liquid Colour amber

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

Remarks • Method **Property** Values

No data available None known Melting point / freezing point 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 No data available

limits

Lower flammability or explosive No data available

limits

Flash point No data available None known No data available **Autoignition temperature**

None known **Decomposition temperature** None known pН

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

Kinematic viscosity No data available None known No data available **Dynamic viscosity** None known Water solubility Miscible in water

Solubility(ies) No data available None known Partition coefficient No data available None known Vapour pressure No data available None known

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Relative density 1 None known

Bulk density
No data available
Liquid Density
No data available
Vapour density
No data available

Particle characteristics

Particle Size Distribution

Particle Size

No information available 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
Avoid contact with metals. This product contains Sodium azide. Sodium azide can react with

Copper, Brass, Lead, and solder in piping systems to form explosive compounds and toxic

None known

gases.

10.4. Conditions to avoid

Conditions to avoidNone known based on information supplied.

10.5. Incompatible materials

Incompatible materials Metals.

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).

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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

Ingestion

Numerical measures of toxicity

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Sodium benzoate	= 4070 mg/kg (Rat)	-	-
Sodium azide	= 27 mg/kg (Rat)	= 20 mg/kg (Rabbit)	0.054 - 0.52 mg/L (Rat) 4 h
5-Chloro-2-methyl-3(2H)-isothia zolone, 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/irritationNo 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 No information available.

11.2.2. Other information

Other adverse effects No information available.

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SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity Harmful to aquatic life with long lasting effects.

Unknown aquatic toxicityContains 0.005 % of components with unknown hazards to the aquatic environment.

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Sodium benzoate	-	LC50: 420 - 558mg/L (96h, Pimephales promelas) LC50: >100mg/L (96h, Pimephales promelas)	-	EC50: <650mg/L (48h, Daphnia magna)
Sodium azide	-	LC50: =0.8mg/L (96h, Oncorhynchus mykiss) LC50: =0.7mg/L (96h, Lepomis macrochirus) LC50: =5.46mg/L (96h, Pimephales promelas)	-	-

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation

Component Information

Chemical name	Partition coefficient				
Sodium benzoate	-2.13				
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with	0.7				
2-methyl-3(2H)-isothiazolone					

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.

Chemical name	PBT and vPvB assessment
Sodium benzoate	The substance is not PBT / vPvB
Sodium azide	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

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Waste from residues/unused

products

Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation. Flush pipes with water frequently if discarding solutions

containing Sodium azide into metal piping systems.

Contaminated packaging Do not reuse empty containers.

SECTION 14: Transport information

IATA

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

14.6 Special Precautions for Users

Special Provisions None

IMDG

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

14.6 Special Precautions for Users

Special Provisions None

14.7 Maritime transport in bulk No information available

according to IMO instruments

RID

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

14.6 Special Precautions for Users

Special Provisions None

ADR

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 Users

Special Provisions None

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) obviously hazardous to water (WGK 2)

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

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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
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

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

<u>International Inventories</u> 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

EUH032 - Contact with acids liberates very toxic gas

EUH071 - Corrosive to the respiratory tract

H300 - Fatal if swallowed

H301 - Toxic if swallowed

H310 - Fatal in contact with skin

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

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

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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 16-Mar-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

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