KIT SAFETY DATA SHEET



Kit Product Name Pastorex Meningitis

Kit Catalogue Number(s) 61607, 12016295

Revision date 04-Aug-2023

Kit Contents

Catalogue Number(s)	Product Name
6178E, 12016505	R5 Pastorex Meningitis Streptococcus B Latex
6178D, 12016497	R4 Pastorex Meningitis S. pneumoniae Latex
6178C,12016537	R3 Pastorex Meningitis H. influenzae B Latex
6160H, 12016365	R2 Pastorex Meningitis N.meningitidis B/E.coli K1
	Negative control Latex
6178J, 12016507	R9 Pastorex Meningitis Negative polyvalent control Latex
6178Q, 12016508	R10 Pastorex Meningitis Positive polyvalent control
	Antigenic extract
6178H, 12016506	R8 Pastorex Meningitis N. meningitidis Y/W135 Latex
6178F, 12016498	R6 Pastorex Meningitis N. meningitidis A Latex
6178G, 12016538	R7 Pastorex Meningitis N. meningitidis C Latex
6160B, 12016504	R1 Pastorex Meningitis N.meningitidis B/E.coli K1 Latex

KITL / EN Page 1/100



SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of: UK REACH Regulations (SI 2019/758 as amended)

The Junction

Station Road

UK

Watford, WD17 1ET

Revision Number 1 Revision date 20-May-2022

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

1.1. Product identifier

Product Name R5 Pastorex Meningitis Streptococcus B Latex

6178E, 12016505 Catalogue Number(s)

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 Restricted to professional users In vitro diagnostic

Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

Legal Entity / Contact Address Corporate Headquarters Manufacturer Bio-Rad Laboratories Ltd

Bio-Rad Laboratories Inc. Bio-Rad 1000 Alfred Nobel Drive 3 boulevard Raymond Poincaré Hercules, CA 94547 92430 Marnes-la-Coquette USA

France

e-mail: fds-msds.fr@bio-rad.com

Technical Service 00800 00246 723

Techsupport.UK@bio-rad.com

1.4. Emergency telephone number

For further information, please contact

24 Hour Emergency Phone Number CHEMTREC UK: 44-870-8200418

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Precautionary statements

P261 - Avoid breathing dust/fume/gas/mist/vapours/spray

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

P362 + P364 - Take off contaminated clothing and wash it before reuse

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

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

2.3. Other hazards

Contains animal source material. (Cattle). Harmful to aquatic life.

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Chemical name	Weight-%	EC No (EU Index No)	UK REACH registration number	Classification according to GB CLP (SI 2020/1567 as amended)	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Sucrose 57-50-1	2.5 - 5	200-334-9	-	-	-	-	-
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothi azolone 55965-84-9	0.001 - 0.01	(613-167-00-5)	-	Acute Tox. 3 (H311) Acute Tox. 3 (H331)	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

Full text of H- and EUH-phrases: see section 16

This product does not contain candidate substances of very high concern at a concentration >= 0.1% (UK 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.

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Revision date 20-May-2022

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 doctorsMay 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. Ensure adequate ventilation. Use personal

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

from and upwind of spill/leak.

6.2. Environmental precautions

Environmental precautions See Section 12 for additional Ecological Information.

6.3. Methods and material for containment and cleaning up

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

Methods for cleaning 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

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.

Wash hands before breaks and immediately after handling the product. General hygiene considerations

7.2. Conditions for safe storage, including any incompatibilities

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

product and label instructions.

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	United Kingdom
Sucrose	TWA: 10 mg/m ³
57-50-1	STEL: 20 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.

No information available. **Derived No Effect Level (DNEL)**

Predicted No Effect Concentration

(PNEC)

No information available.

8.2. Exposure controls

No information available. **Engineering 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.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Liquid Physical state Liquid **Appearance** Colour yellow Odour Odourless.

Odour threshold No information available

Property Values Remarks • Method

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 No data available

limits

Lower flammability or explosive No data available

limits

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

Decomposition temperature pН

None known None known

None known

Revision date 20-May-2022

pH (as aqueous solution) No data available Kinematic viscosity No data available None known Dynamic viscosity No data available 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

No data available Relative density No data available **Bulk density 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

SECTION 10: Stability and reactivity

10.1. Reactivity

No information available. Reactivity

10.2. Chemical stability

Stability Stable under normal conditions.

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

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. Toxicological information

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

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Sucrose	= 29700 mg/kg (Rat)	-	-
5-Chloro-2-methyl-3(2H)-isothia	= 53 mg/kg (Rat)	= 87.12 mg/kg (Rabbit)	-
zolone, mixture with			
2-methyl-3(2H)-isothiazolone			

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

Skin corrosion/irritation No information available.

No information available. Serious eye damage/eye irritation

Respiratory or skin sensitisation May cause an allergic skin reaction.

No information available. Germ cell mutagenicity

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. Other adverse effects No information available.

SECTION 12: Ecological information

12.1. Toxicity

Harmful to aquatic life with long lasting effects. **Ecotoxicity**

Unknown aquatic toxicity Contains 0 % of components with unknown hazards to the aquatic environment.

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	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

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

12.6. Endocrine disrupting properties

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

R5 Pastorex Meningitis Streptococcus B Latex

Revision date 20-May-2022

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

<u>ADR</u>

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
440	Cuncial Decourtions for House	

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

Authorisations and/or restrictions on use:

This product does not contain substances subject to authorisation (UK REACH - Annex XIV). This product does not contain substances subject to restriction (UK REACH - Annex XVII).

Persistent Organic Pollutants

Not applicable

Export Notification requirements

Not applicable

Named dangerous substances per COMAH Regulations 2015 (as amended)

Not applicable

The Ozone-Depleting Substances Regulations 2015

Not applicable

The Biocidal Products Regulations 2001 (as amended)

Chemical name	The Biocidal Products Regulations 2001 (as amended)
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with	PT02 - Disinfectants and algaecides not intended for direct
2-methyl-3(2H)-isothiazolone - 55965-84-9	application to humans or animals

R5 Pastorex Meningitis Streptococcus B Latex

PT06 - Preservatives for products during storage
PT13 - Working or cutting fluid preservatives
PT04 - Food and feed area
PT11 - Preservatives for liquid-cooling and processing
systems
PT12 - Slimicides

Revision date 20-May-2022

The Water Environment (Water Framework Directive) (England and Wales) Regulations 2017 (as amended) Not applicable

Poisons Act 1972 (Explosive Precursors) Regulations (as Amended)

Not applicable

<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

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

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

+ Sensitisers

Classification procedure

Classification according to Regulation (EC) No. 1272/2008 [CLP] Method Used Calculation method Acute oral toxicity 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 Calculation method Skin sensitisation 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

R5 Pastorex Meningitis Streptococcus B Latex

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Revision date 20-May-2022

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 date

20-May-2022

Revision Note

Significant changes throughout SDS. Review all sections

This material safety data sheet complies with the requirements of UK REACH Regulations (SI 2019/758 as amended) 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

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



SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of: UK REACH Regulations (SI 2019/758 as amended)

The Junction

Station Road

UK

Watford, WD17 1ET

Revision date 20-May-2022 Revision Number 1

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

1.1. Product identifier

Product Name R4 Pastorex Meningitis S. pneumoniae Latex

Catalogue Number(s) 6178D, 12016497

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 Restricted to professional users In vitro diagnostic

Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

Corporate HeadquartersManufacturerLegal Entity / Contact AddressBio-Rad Laboratories Inc.Bio-RadBio-Rad Laboratories Ltd

1000 Alfred Nobel Drive 3 boulevard Raymond Poincaré
Hercules, CA 94547 92430 Marnes-la-Coquette

USA France

e-mail: fds-msds.fr@bio-rad.com

Technical Service 00800 00246 723

Techsupport.UK@bio-rad.com

1.4. Emergency telephone number

For further information, please contact

24 Hour Emergency Phone Number CHEMTREC UK: 44-870-8200418

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Precautionary statements

P261 - Avoid breathing dust/fume/gas/mist/vapours/spray

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

P362 + P364 - Take off contaminated clothing and wash it before reuse

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

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

2.3. Other hazards

Contains animal source material. (Cattle). Harmful to aquatic life.

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Chemical name	Weight-%	EC No (EU Index No)	UK REACH registration number	Classification according to GB CLP (SI 2020/1567 as amended)	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Sucrose 57-50-1	2.5 - 5	200-334-9	-	-	-	-	-
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothi azolone 55965-84-9		(613-167-00-5)	-	Acute Tox. 3 (H311) Acute Tox. 3 (H331)	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

Full text of H- and EUH-phrases: see section 16

This product does not contain candidate substances of very high concern at a concentration >= 0.1% (UK 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.

Wash with soap and water. May cause an allergic skin reaction. In the case of skin irritation Skin contact

or allergic reactions see a doctor.

Ingestion Rinse mouth.

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

Itching. Rashes. Hives. **Symptoms**

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.

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

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

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.

For emergency responders Use personal protection recommended in Section 8.

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 Prevent further leakage or spillage if safe to do so.

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

Clean contaminated objects and areas thoroughly observing environmental regulations. Prevention of secondary hazards

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.

Wash hands before breaks and immediately after handling the product. General hygiene considerations

7.2. Conditions for safe storage, including any incompatibilities

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

product and label instructions.

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	United Kingdom	
Sucrose	TWA: 10 mg/m ³	
57-50-1	STEL: 20 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.

No information available. **Derived No Effect Level (DNEL)**

Predicted No Effect Concentration

(PNEC)

No information available.

8.2. Exposure controls

No information available. **Engineering 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.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state Liquid
Appearance Liquid
Colour green
Odour Odourless.

Odour threshold No information available

<u>Property</u> <u>Values</u> <u>Remarks • Method</u>

Melting point / freezing pointNo data availableNone knownBoiling point / boiling rangeNo data availableNone knownFlammability (solid, gas)No data availableNone knownFlammability Limit in AirNone known

Upper flammability or explosive No data available

limits

Lower flammability or explosive No data available

limits

Flash point No data available None known
Autoignition temperature No data available None known
Decomposition temperature
pH None known
None known

pH (as aqueous solution)

No data available

None known

Water solubility Miscible in water
Solubility(ies) No data available

Solubility(ies)No data availableNone knownPartition coefficientNo data availableNone knownVapour pressureNo data availableNone knownRelative densityNo data availableNone known

Bulk density No data available Liquid Density No data available

Vapour densityNo data availableNone known

Particle characteristics

Particle Size No information available Particle Size Distribution No information available

9.2. Other information

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. Toxicological information

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

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Sucrose	= 29700 mg/kg (Rat)	-	-
5-Chloro-2-methyl-3(2H)-isothia	= 53 mg/kg (Rat)	= 87.12 mg/kg (Rabbit)	-
zolone, mixture with			
2-methyl-3(2H)-isothiazolone			

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

Skin corrosion/irritation No information available.

No information available. Serious eye damage/eye irritation

Respiratory or skin sensitisation May cause an allergic skin reaction.

No information available. Germ cell mutagenicity

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. Other adverse effects No information available.

SECTION 12: Ecological information

12.1. Toxicity

Harmful to aquatic life with long lasting effects. **Ecotoxicity**

Unknown aquatic toxicity Contains 0 % of components with unknown hazards to the aquatic environment.

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	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

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

12.6. Endocrine disrupting properties

No information available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues/unused

Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

products

Contaminated packaging Do not reuse empty containers.

SECTION 14: Transport information

IATA

R4 Pastorex Meningitis S. pneumoniae Latex

Revision date 20-May-2022

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 No information available according to IMO instruments

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 Not regulated 14.2 UN proper shipping name 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

Authorisations and/or restrictions on use:

This product does not contain substances subject to authorisation (UK REACH - Annex XIV). This product does not contain substances subject to restriction (UK REACH - Annex XVII).

Persistent Organic Pollutants

Not applicable

Export Notification requirements

Not applicable

Named dangerous substances per COMAH Regulations 2015 (as amended)

Not applicable

The Ozone-Depleting Substances Regulations 2015

Not applicable

The Biocidal Products Regulations 2001 (as amended)

Chemical name	The Biocidal Products Regulations 2001 (as amended)
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with	PT02 - Disinfectants and algaecides not intended for direct
2-methyl-3(2H)-isothiazolone - 55965-84-9	application to humans or animals

R4 Pastorex Meningitis S. pneumoniae Latex

PT06 - Preservatives for products during storage
PT13 - Working or cutting fluid preservatives
PT04 - Food and feed area
PT11 - Preservatives for liquid-cooling and processing
systems
PT12 - Slimicides

Revision date 20-May-2022

The Water Environment (Water Framework Directive) (England and Wales) Regulations 2017 (as amended) Not applicable

Poisons Act 1972 (Explosive Precursors) Regulations (as Amended)

Not applicable

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

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

+ Sensitisers

Classification procedure

Classification according to Regulation (EC) No. 1272/2008 [CLP] Method Used Calculation method Acute oral toxicity 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 Calculation method Skin sensitisation 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

R4 Pastorex Meningitis S. pneumoniae Latex

Revision date 20-May-2022

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 date

20-May-2022

Revision Note

Significant changes throughout SDS. Review all sections

This material safety data sheet complies with the requirements of UK REACH Regulations (SI 2019/758 as amended) 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

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



SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of: UK REACH Regulations (SI 2019/758 as amended)

The Junction

Station Road

UK

Watford, WD17 1ET

Revision Number 1 Revision date 20-May-2022

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

1.1. Product identifier

Product Name R3 Pastorex Meningitis H. influenzae B Latex

6178C,12016537 Catalogue Number(s)

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 Restricted to professional users In vitro diagnostic

Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

Legal Entity / Contact Address Corporate Headquarters Manufacturer Bio-Rad Laboratories Ltd

Bio-Rad Laboratories Inc. Bio-Rad 1000 Alfred Nobel Drive 3 boulevard Raymond Poincaré Hercules, CA 94547 92430 Marnes-la-Coquette USA

France

e-mail: fds-msds.fr@bio-rad.com

00800 00246 723

Technical Service Techsupport.UK@bio-rad.com

1.4. Emergency telephone number

For further information, please contact

24 Hour Emergency Phone Number CHEMTREC UK: 44-870-8200418

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Precautionary statements

P261 - Avoid breathing dust/fume/gas/mist/vapours/spray

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

P362 + P364 - Take off contaminated clothing and wash it before reuse

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

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

2.3. Other hazards

Contains animal source material. (Cattle). Harmful to aquatic life.

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Chemical name	Weight-%	EC No (EU Index No)	UK REACH registration number	Classification according to GB CLP (SI 2020/1567 as amended)	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Sucrose 57-50-1	2.5 - 5	200-334-9	-	-	-	-	-
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothi azolone 55965-84-9	0.01 - 0.099	(613-167-00-5)	-	Acute Tox. 3 (H311) Acute Tox. 3 (H331)	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

Full text of H- and EUH-phrases: see section 16

This product does not contain candidate substances of very high concern at a concentration >= 0.1% (UK 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.

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Revision date 20-May-2022

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 doctorsMay 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. Ensure adequate ventilation. Use personal

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

from and upwind of spill/leak.

6.2. Environmental precautions

Environmental precautions See Section 12 for additional Ecological Information.

6.3. Methods and material for containment and cleaning up

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

Methods for cleaning 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 sectionsSee 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. Ensure adequate ventilation. In case of insufficient ventilation, wear suitable respiratory equipment. Do not eat, drink or smoke when using this product. Take off

Revision date 20-May-2022

contaminated clothing and wash it before reuse.

General hygiene considerations Wash hands before breaks and immediately after handling the product.

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.

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	United Kingdom		
Sucrose	TWA: 10 mg/m ³		
57-50-1	STEL: 20 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)

No information available.

8.2. Exposure controls

Engineering controls No information available.

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.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state
Appearance
Colour
Odour

Diquid
White
Odourless.

Odour threshold No information available

<u>Property</u> <u>Values</u> <u>Remarks • Method</u>

Melting point / freezing pointNo data availableNone knownBoiling point / boiling rangeNo data availableNone knownFlammability (solid, gas)No data availableNone knownFlammability Limit in AirNone known

Upper flammability or explosive No data available

limits

Lower flammability or explosive No data available

limits

Flash point No data available None known Autoignition temperature No data available None known Decomposition temperature PH None known None known

pHNone knownpH (as aqueous solution)No data availableNone knownKinematic viscosityNo data availableNone knownDynamic viscosityNo data availableNone known

Dynamic viscosity No data available Water solubility No data available Miscible in water

Solubility(ies)No data availableNone knownPartition coefficientNo data availableNone knownVapour pressureNo data availableNone knownRelative densityNo data availableNone known

Bulk density
No data available
No data available

Vapour densityNo data availableNone known

Particle characteristics

Particle Size No information available Particle Size Distribution No information available

9.2. Other information

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 materialsNone 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. Toxicological information

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

Revision date 20-May-2022

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

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Sucrose	= 29700 mg/kg (Rat)	-	-
5-Chloro-2-methyl-3(2H)-isothia	= 53 mg/kg (Rat)	= 87.12 mg/kg (Rabbit)	-
zolone, mixture with			
2-methyl-3(2H)-isothiazolone			

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 exposureNo information available.

Aspiration hazard No information available.

Other adverse effects No information available.

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity Harmful to aquatic life with long lasting effects.

Unknown aquatic toxicityContains 0 % of components with unknown hazards to the aquatic environment.

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	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

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

12.6. Endocrine disrupting properties

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

R3 Pastorex Meningitis H. influenzae B Latex

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Revision date 20-May-2022

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
440	Cuncial Decourtions for House	

14.6 Special Precautions for Users

Special Provisions None

IMDG

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

14.7 Maritime transport in bulk according to IMO instruments

No information available

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

Authorisations and/or restrictions on use:

This product does not contain substances subject to authorisation (UK REACH - Annex XIV). This product does not contain substances subject to restriction (UK REACH - Annex XVII).

Persistent Organic Pollutants

Not applicable

Export Notification requirements

Not applicable

Named dangerous substances per COMAH Regulations 2015 (as amended)

Not applicable

The Ozone-Depleting Substances Regulations 2015

Not applicable

The Biocidal Products Regulations 2001 (as amended)

Chemical name	The Biocidal Products Regulations 2001 (as amended)
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with	PT02 - Disinfectants and algaecides not intended for direct
2-methyl-3(2H)-isothiazolone - 55965-84-9	application to humans or animals

R3 Pastorex Meningitis H. influenzae B Latex

PT06 - Preservatives for products during storage
PT13 - Working or cutting fluid preservatives
PT04 - Food and feed area
PT11 - Preservatives for liquid-cooling and processing
systems
PT12 - Slimicides

Revision date 20-May-2022

The Water Environment (Water Framework Directive) (England and Wales) Regulations 2017 (as amended) Not applicable

Poisons Act 1972 (Explosive Precursors) Regulations (as Amended)

Not applicable

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

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

+ Sensitisers

Classification procedure

Classification according to Regulation (EC) No. 1272/2008 [CLP] Method Used Calculation method Acute oral toxicity 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 Calculation method Skin sensitisation 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 date

20-May-2022

Revision Note

Significant changes throughout SDS. Review all sections

This material safety data sheet complies with the requirements of UK REACH Regulations (SI 2019/758 as amended) 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

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



SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of: UK REACH Regulations (SI 2019/758 as amended)

The Junction

Station Road

Watford, WD17 1ET

Revision date 20-May-2022 Revision Number 1

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

1.1. Product identifier

Product Name R2 Pastorex Meningitis N.meningitidis B/E.coli K1 Negative control Latex

Catalogue Number(s) 6160H, 12016365

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 Restricted to professional users In vitro diagnostic

Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

Corporate HeadquartersManufacturerLegal Entity / Contact AddressBio-Rad Laboratories Inc.Bio-RadBio-Rad Laboratories Ltd

Bio-Rad Laboratories Inc.

1000 Alfred Nobel Drive

Hercules, CA 94547

Bio-Rad

3 boulevard Raymond Poincaré

92430 Marnes-la-Coquette

USA France

e-mail: fds-msds.fr@bio-rad.com UK

Technical Service 00800 00246 723

Techsupport.UK@bio-rad.com

1.4. Emergency telephone number

For further information, please contact

24 Hour Emergency Phone Number CHEMTREC UK: 44-870-8200418

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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



R2 Pastorex Meningitis N.meningitidis B/E.coli K1 Negative control Latex

negative control Latex

Revision date 20-May-2022

Signal word

Warning

Hazard statements

H317 - May cause an allergic skin reaction

H412 - Harmful to aquatic life with long lasting effects

Precautionary statements

P261 - Avoid breathing dust/fume/gas/mist/vapours/spray

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

P362 + P364 - Take off contaminated clothing and wash it before reuse

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

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

2.3. Other hazards

Contains animal source material. (Cattle). Harmful to aquatic life.

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Chemical name	Weight-%	EC No (EU Index No)	UK REACH registration number	Classification according to GB CLP (SI 2020/1567 as amended)	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Sucrose 57-50-1	2.5 - 5	200-334-9	-	-	-	1	1
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothi azolone 55965-84-9	0.001 - 0.01	(613-167-00-5)	-	Acute Tox. 3 (H311) Acute Tox. 3 (H331)	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

Full text of H- and EUH-phrases: see section 16

This product does not contain candidate substances of very high concern at a concentration >= 0.1% (UK REACH Article 59)

SECTION 4: First aid measures

4.1. Description of first aid measures

R2 Pastorex Meningitis N.meningitidis B/E.coli K1 Negative control Latex

Revision date 20-May-2022

General advice Show this safety data sheet to the doctor in attendance.

Inhalation Remove to fresh air.

Eye contactRinse 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.

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. Ensure adequate ventilation. Use personal

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

from and upwind of spill/leak.

For emergency responders

Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions See Section 12 for additional Ecological Information.

6.3. Methods and material for containment and cleaning up

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

R2 Pastorex Meningitis N.meningitidis B/E.coli K1 Negative control Latex

Revision date 20-May-2022

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. 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 Wash hands before breaks and immediately after handling the product.

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.

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	United Kingdom
Sucrose	TWA: 10 mg/m ³
57-50-1	STEL: 20 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

No information available.

(PNEC)

8.2. Exposure controls

Engineering controls No information available.

Personal protective equipment

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

Hand protection Wear suitable 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.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Liquid Physical state **Appearance** Liquid Colour red Odourless. Odour

Odour threshold No information available

Property Values Remarks • Method

No data available **Melting point / freezing point** 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 No data available

limits

Lower flammability or explosive No data available

limits

Flash point No data available None known **Autoignition temperature** No data available None known **Decomposition temperature** None known None known pH (as aqueous solution) No data available None known 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 No data available None known Vapour pressure No data available Relative density 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

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

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions None under normal processing.

R2 Pastorex Meningitis N.meningitidis B/E.coli K1 Negative control Latex

3....

10.4. Conditions to avoid

Conditions to avoid None known based on information supplied.

10.5. Incompatible materials

Incompatible materialsNone 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. Toxicological information

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

Revision date 20-May-2022

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

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Sucrose	= 29700 mg/kg (Rat)	-	-
5-Chloro-2-methyl-3(2H)-isothia	= 53 mg/kg (Rat)	= 87.12 mg/kg (Rabbit)	-
zolone, mixture with 2-methyl-3(2H)-isothiazolone			

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 toxicityNo information available.

STOT - single exposure No information available.

STOT - repeated exposureNo information available.

Aspiration hazard No information available.

Other adverse effects No information available.

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity Harmful to aquatic life with long lasting effects.

Unknown aquatic toxicityContains 0 % of components with unknown hazards to the aquatic environment.

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	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

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

12.6. Endocrine disrupting properties

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

IATA

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

14.6 Special Precautions for Users

Special Provisions None

IMDG

14.1 UN number or ID number Not regulated Not regulated 14.2 UN proper shipping name 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 No information available according to IMO instruments

RID

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

14.6 Special Precautions for Users

Special Provisions None

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

Authorisations and/or restrictions on use:

This product does not contain substances subject to authorisation (UK REACH - Annex XIV). This product does not contain substances subject to restriction (UK REACH - Annex XVII).

Persistent Organic Pollutants

Not applicable

Export Notification requirements

Not applicable

Named dangerous substances per COMAH Regulations 2015 (as amended)

Not applicable

The Ozone-Depleting Substances Regulations 2015

Not applicable

The Biocidal Products Regulations 2001 (as amended)

Chemical name	The Biocidal Products Regulations 2001 (as amended)
	PT02 - Disinfectants and algaecides not intended for direct
2-methyl-3(2H)-isothiazolone - 55965-84-9	application to humans or animals
	PT06 - Preservatives for products during storage
	PT13 - Working or cutting fluid preservatives
	PT04 - Food and feed area
	PT11 - Preservatives for liquid-cooling and processing
	systems
	PT12 - Slimicides

The Water Environment (Water Framework Directive) (England and Wales) Regulations 2017 (as amended) Not applicable

Poisons Act 1972 (Explosive Precursors) Regulations (as Amended)

Not applicable

<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

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

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

+ Sensitisers

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 date 20-May-2022

Revision Note

Significant changes throughout SDS. Review all sections

This material safety data sheet complies with the requirements of UK REACH Regulations (SI 2019/758 as amended) 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

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



SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of: UK REACH Regulations (SI 2019/758 as amended)

The Junction

Station Road

UK

Watford, WD17 1ET

Revision Number 1 Revision date 20-May-2022

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

1.1. Product identifier

Product Name R9 Pastorex Meningitis Negative polyvalent control Latex

6178J, 12016507 Catalogue Number(s)

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 Restricted to professional users In vitro diagnostic

Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

Legal Entity / Contact Address Corporate Headquarters Manufacturer Bio-Rad Laboratories Ltd

Bio-Rad Laboratories Inc. Bio-Rad 1000 Alfred Nobel Drive 3 boulevard Raymond Poincaré Hercules, CA 94547 92430 Marnes-la-Coquette

USA France

e-mail: fds-msds.fr@bio-rad.com

00800 00246 723

Technical Service Techsupport.UK@bio-rad.com

1.4. Emergency telephone number

For further information, please contact

24 Hour Emergency Phone Number CHEMTREC UK: 44-870-8200418

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Precautionary statements

P261 - Avoid breathing dust/fume/gas/mist/vapours/spray

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

P362 + P364 - Take off contaminated clothing and wash it before reuse

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

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

2.3. Other hazards

Contains animal source material. (Cattle). Harmful to aquatic life.

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Chemical name	Weight-%	EC No (EU Index No)	UK REACH registration number	Classification according to GB CLP (SI 2020/1567 as amended)	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Sucrose 57-50-1	2.5 - 5	200-334-9	-	-	-	-	-
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothi azolone 55965-84-9	0.001 - 0.01	(613-167-00-5)	-	Acute Tox. 3 (H311) Acute Tox. 3 (H331)	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

Full text of H- and EUH-phrases: see section 16

This product does not contain candidate substances of very high concern at a concentration >= 0.1% (UK REACH Article 59)

SECTION 4: First aid measures

4.1. Description of first aid measures

R9 Pastorex Meningitis Negative polyvalent control Latex

Revision date 20-May-2022

General advice Show this safety data sheet to the doctor in attendance.

Inhalation Remove to fresh air.

Eye contactRinse 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

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. Ensure adequate ventilation. Use personal

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

from and upwind of spill/leak.

For emergency responders

Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions See Section 12 for additional Ecological Information.

6.3. Methods and material for containment and cleaning up

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

R9 Pastorex Meningitis Negative polyvalent control Latex

Revision date 20-May-2022

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 sectionsSee 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. 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 Wash hands before breaks and immediately after handling the product.

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.

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	United Kingdom
Sucrose	TWA: 10 mg/m ³
57-50-1	STEL: 20 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)

No information available.

8.2. Exposure controls

Engineering controls No information available.

Personal protective equipment

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

Hand protection Wear suitable gloves.

Skin and body protectionWear suitable protective clothing.

Respiratory protectionNo protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state Liquid
Appearance Liquid
Colour violet
Odour Odourless.

Odour threshold No information available

<u>Property</u> <u>Values</u> <u>Remarks • Method</u>

Melting point / freezing pointNo data availableNone knownBoiling point / boiling rangeNo data availableNone knownFlammability (solid, gas)No data availableNone knownFlammability Limit in AirNone known

Upper flammability or explosive No data available

limits

Lower flammability or explosive No data available

limits

Flash point No data available None known
Autoignition temperature No data available None known
Decomposition temperature
pH
pH (as aqueous solution) No data available None known
None known
None known
None known

pH (as aqueous solution)No data availableNone knownKinematic viscosityNo data availableNone knownDynamic viscosityNo data availableNone known

Water solubility Miscible in water

Solubility(ies)No data availableNone knownPartition coefficientNo data availableNone knownVapour pressureNo data availableNone knownRelative densityNo data availableNone known

Bulk density
No data available
Liquid Density
No data available

Vapour density No data available None known

Particle characteristics

Particle SizeNo information availableParticle Size DistributionNo information available

9.2. Other information

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.

R9 Pastorex Meningitis Negative polyvalent control Latex

10.4. Conditions to avoid

Conditions to avoid None known based on information supplied.

10.5. Incompatible materials

Incompatible materialsNone 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. Toxicological information

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

Revision date 20-May-2022

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

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Sucrose	= 29700 mg/kg (Rat)	-	-
5-Chloro-2-methyl-3(2H)-isothia	= 53 mg/kg (Rat)	= 87.12 mg/kg (Rabbit)	-
zolone, mixture with 2-methyl-3(2H)-isothiazolone			

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.

STOT - single exposure No information available.

STOT - repeated exposureNo information available.

Aspiration hazard No information available.

Other adverse effects No information available.

SECTION 12: Ecological information

12.1. Toxicity

Reproductive toxicity

Ecotoxicity Harmful to aquatic life with long lasting effects.

No information available.

Unknown aquatic toxicityContains 0 % of components with unknown hazards to the aquatic environment.

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	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

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

12.6. Endocrine disrupting properties

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 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

<u>IMDG</u>

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

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

14.6 Special Precautions for Users

Special Provisions None

<u>ADR</u>

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

SECTION 15: Regulatory information

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

National regulations

Authorisations and/or restrictions on use:

This product does not contain substances subject to authorisation (UK REACH - Annex XIV). This product does not contain substances subject to restriction (UK REACH - Annex XVII).

Persistent Organic Pollutants

Not applicable

Export Notification requirements

Not applicable

Named dangerous substances per COMAH Regulations 2015 (as amended)

Not applicable

The Ozone-Depleting Substances Regulations 2015

Latex

Not applicable

The Biocidal Products Regulations 2001 (as amended)

Chemical name	The Biocidal Products Regulations 2001 (as amended)
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with	PT02 - Disinfectants and algaecides not intended for direct
2-methyl-3(2H)-isothiazolone - 55965-84-9	application to humans or animals
	PT06 - Preservatives for products during storage
	PT13 - Working or cutting fluid preservatives
	PT04 - Food and feed area
	PT11 - Preservatives for liquid-cooling and processing
	systems
	PT12 - Slimicides

The Water Environment (Water Framework Directive) (England and Wales) Regulations 2017 (as amended) Not applicable

Poisons Act 1972 (Explosive Precursors) Regulations (as Amended)

Not applicable

<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

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

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

+ Sensitisers

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
Calculation method
Calculation method
Calculation method
Calculation method
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 date 20-May-2022

Revision Note S

Significant changes throughout SDS. Review all sections

This material safety data sheet complies with the requirements of UK REACH Regulations (SI 2019/758 as amended) 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

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



SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of: UK REACH Regulations (SI 2019/758 as amended)

The Junction

Station Road

UK

Watford, WD17 1ET

Revision date 20-May-2022 Revision Number 1

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

1.1. Product identifier

Product Name R10 Pastorex Meningitis Positive polyvalent control Antigenic extract

Catalogue Number(s) 6178Q, 12016508

Pure substance/mixture Mixture

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

Recommended use Restricted to professional users In vitro diagnostic

Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

Corporate HeadquartersManufacturerLegal Entity / Contact AddressBio-Rad Laboratories Inc.Bio-RadBio-Rad Laboratories Ltd

Bio-Rad Laboratories Inc.

Bio-Rad

1000 Alfred Nobel Drive

Hercules, CA 94547

Bio-Rad

3 boulevard Raymond Poincaré

92430 Marnes-la-Coquette

USA France

e-mail: fds-msds.fr@bio-rad.com

For further information, please contact

Technical Service 00800 00246 723

Techsupport.UK@bio-rad.com

1.4. Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC UK: 44-870-8200418

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Not classified Not a hazardous substance or mixture according to the Globally Harmonised System (GHS)

2.2. Label elements

Not classified Not a hazardous substance or mixture according to the Globally Harmonised System (GHS)

Hazard statements

Not classified Not a hazardous substance or mixture according to the Globally Harmonised System (GHS)

2.3. Other hazards

SECTION 3: Composition/information on ingredients

3.1 Substances

Antigenic extract

Revision date 20-May-2022

Not applicable

3.2 Mixtures

The product contains no substances which at their given concentration, are considered to be hazardous to health

Full text of H- and EUH-phrases: see section 16

This product does not contain candidate substances of very high concern at a concentration >= 0.1% (UK REACH Article 59)

SECTION 4: First aid measures

4.1. Description of first aid measures

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 In the case of skin irritation or allergic reactions see a doctor. Wash skin with soap and

water.

Ingestion Rinse mouth.

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

Symptoms No information available.

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

Note to doctors 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 mediaDo 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

No information available.

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

R10 Pastorex Meningitis Positive polyvalent control Antigenic extract

Revision date 20-May-2022

Personal precautions Ensure adequate ventilation.

For emergency responders

Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions See Section 12 for additional Ecological Information.

6.3. Methods and material for containment and cleaning up

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

Methods for cleaning 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 Ensure adequate ventilation.

General hygiene considerations Wash hands before breaks and immediately after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store according to product and label instructions.

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)No information available.

Predicted No Effect Concentration

(PNEC)

No information available.

8.2. Exposure controls

Engineering controls No information available.

Personal protective equipment

Eye/face protection No special protective equipment required.

Skin and body protection No special protective equipment required.

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.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state Solid **Appearance** Powder Colour white Odour Odourless.

Odour threshold No information available

Property Values Remarks • Method

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

No data available Upper flammability or explosive

limits

Lower flammability or explosive No data available

limits

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

Decomposition temperature None known None known

pH (as aqueous solution) No data available None known Kinematic viscosity No data available None known **Dynamic viscosity** No data available None known

Water solubility Insoluble in water No data available None known Solubility(ies) Partition coefficient No data available None known Vapour pressure No data available None known No data available Relative density 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

SECTION 10: Stability and reactivity

10.1. Reactivity

No information available. Reactivity

10.2. Chemical stability

Stable under normal conditions. Stability

Explosion data

R10 Pastorex Meningitis Positive polyvalent control Antigenic extract

Revision date 20-May-2022

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 materialsNone 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. Toxicological information

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

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

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms No information available.

Acute toxicity

Numerical measures of toxicity

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 No information available.

Germ cell mutagenicity No information available.

Carcinogenicity No information available.

R10 Pastorex Meningitis Positive polyvalent control **Antigenic extract**

Revision date 20-May-2022

Reproductive toxicity No information available.

STOT - single exposure No information available.

STOT - repeated exposure No information available.

No information available. **Aspiration hazard** Other adverse effects No information available.

SECTION 12: Ecological information

12.1. Toxicity

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

Unknown aquatic toxicity Contains 0.33 % of components with unknown hazards to the aquatic environment.

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation There is no data for this product.

12.4. Mobility in soil

No information available. Mobility in soil

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment

12.6. Endocrine disrupting properties

No information available.

SECTION 13: Disposal considerations

Dispose of in accordance with local regulations. Dispose of waste in accordance with

13.1. Waste treatment methods

Waste from residues/unused

environmental legislation.

products

Do not reuse empty containers.

Contaminated packaging

SECTION 14: Transport information

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 No information available according to IMO instruments

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

Authorisations and/or restrictions on use:

This product does not contain substances subject to authorisation (UK REACH - Annex XIV). This product does not contain substances subject to restriction (UK REACH - Annex XVII).

Persistent Organic Pollutants

Not applicable

Export Notification requirements

Not applicable

Named dangerous substances per COMAH Regulations 2015 (as amended)

Not applicable

The Ozone-Depleting Substances Regulations 2015

Not applicable

The Biocidal Products Regulations 2001 (as amended)

Not applicable

The Water Environment (Water Framework Directive) (England and Wales) Regulations 2017 (as amended)

Not applicable

Poisons Act 1972 (Explosive Precursors) Regulations (as Amended)

R10 Pastorex Meningitis Positive polyvalent control Antigenic extract

Revision date 20-May-2022

Not applicable

<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

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

+ Sensitisers

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

R10 Pastorex Meningitis Positive polyvalent control Antigenic extract

Revision date 20-May-2022

Organisation for Economic Co-operation and Development Screening Information Data Set World Health Organization

Revision date 20-May-2022

Revision Note Significant changes throughout SDS. Review all sections

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Disclaimer

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End of Safety Data Sheet



SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of: UK REACH Regulations (SI 2019/758 as amended)

UK

Revision date 20-May-2022 Revision Number 1

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

1.1. Product identifier

Product Name R8 Pastorex Meningitis N. meningitidis Y/W135 Latex

Catalogue Number(s) 6178H, 12016506

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 Restricted to professional users In vitro diagnostic

Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

Corporate HeadquartersManufacturerLegal Entity / Contact AddressBio-Rad Laboratories Inc.Bio-RadBio-Rad Laboratories Ltd

Bio-Rad Laboratories Inc.

Bio-Rad

Bio-Rad

Bio-Rad Laboratories

1000 Alfred Nobel Drive

3 boulevard Raymond Poincaré

Hercules, CA 94547

92430 Marnes-la-Coquette

Station Road

Watford, WD17 1ET

e-mail: fds-msds.fr@bio-rad.com

For further information, please contact

Technical Service 00800 00246 723

Techsupport.UK@bio-rad.com

1.4. Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC UK: 44-870-8200418

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Precautionary statements

P261 - Avoid breathing dust/fume/gas/mist/vapours/spray

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

P362 + P364 - Take off contaminated clothing and wash it before reuse

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

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

2.3. Other hazards

Contains animal source material. (Cattle). Harmful to aquatic life.

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Chemical name	Weight-%	EC No (EU Index No)	UK REACH registration number	Classification according to GB CLP (SI 2020/1567 as amended)	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Sucrose 57-50-1	2.5 - 5	200-334-9	-	-	-	1	-
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothi azolone 55965-84-9	0.001 - 0.01	(613-167-00-5)	-	Acute Tox. 3 (H311) Acute Tox. 3 (H331)	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

Full text of H- and EUH-phrases: see section 16

This product does not contain candidate substances of very high concern at a concentration >= 0.1% (UK 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.

Wash with soap and water. May cause an allergic skin reaction. In the case of skin irritation Skin contact

or allergic reactions see a doctor.

Ingestion Rinse mouth.

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

Itching. Rashes. Hives. **Symptoms**

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.

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

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. Ensure adequate ventilation. Use personal

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

from and upwind of spill/leak.

For emergency responders Use personal protection recommended in Section 8.

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 Prevent further leakage or spillage if safe to do so.

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

Clean contaminated objects and areas thoroughly observing environmental regulations. Prevention of secondary hazards

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.

Wash hands before breaks and immediately after handling the product. General hygiene considerations

7.2. Conditions for safe storage, including any incompatibilities

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

product and label instructions.

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	United Kingdom
Sucrose	TWA: 10 mg/m ³
57-50-1	STEL: 20 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.

No information available. **Derived No Effect Level (DNEL)**

Predicted No Effect Concentration

(PNEC)

No information available.

8.2. Exposure controls

No information available. **Engineering 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.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Liquid Physical state Liquid **Appearance** Colour pink Odour Odourless.

Odour threshold No information available

Property Values Remarks • Method

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 No data available

limits

Lower flammability or explosive No data available

limits

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

pH (as aqueous solution) No data available None known Kinematic viscosity No data available None known Dynamic viscosity No data available 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 None known

No data available Relative density No data available **Bulk density 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

SECTION 10: Stability and reactivity

10.1. Reactivity

No information available. Reactivity

10.2. Chemical stability

Stability Stable under normal conditions.

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

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. Toxicological information

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

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Sucrose	= 29700 mg/kg (Rat)	-	-
5-Chloro-2-methyl-3(2H)-isothia zolone, mixture with	= 53 mg/kg (Rat)	= 87.12 mg/kg(Rabbit)	-
2-methyl-3(2H)-isothiazolone			

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

Skin corrosion/irritation No information available.

No information available. Serious eye damage/eye irritation

Respiratory or skin sensitisation May cause an allergic skin reaction.

No information available. Germ cell mutagenicity

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. Other adverse effects No information available.

SECTION 12: Ecological information

12.1. Toxicity

Harmful to aquatic life with long lasting effects. **Ecotoxicity**

Unknown aquatic toxicity Contains 0 % of components with unknown hazards to the aquatic environment.

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	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

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

12.6. Endocrine disrupting properties

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

R8 Pastorex Meningitis N. meningitidis Y/W135 Latex

Revision date 20-May-2022

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 Not regulated 14.2 UN proper shipping name 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 Not regulated 14.2 UN proper shipping name 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

Authorisations and/or restrictions on use:

This product does not contain substances subject to authorisation (UK REACH - Annex XIV). This product does not contain substances subject to restriction (UK REACH - Annex XVII).

Persistent Organic Pollutants

Not applicable

Export Notification requirements

Not applicable

Named dangerous substances per COMAH Regulations 2015 (as amended)

Not applicable

The Ozone-Depleting Substances Regulations 2015

Not applicable

The Biocidal Products Regulations 2001 (as amended)

Chemical name	The Biocidal Products Regulations 2001 (as amended)
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with	PT02 - Disinfectants and algaecides not intended for direct
2-methyl-3(2H)-isothiazolone - 55965-84-9	application to humans or animals

PT06 - Preservatives for products during storage
PT13 - Working or cutting fluid preservatives
PT04 - Food and feed area
PT11 - Preservatives for liquid-cooling and processing
systems
PT12 - Slimicides

Revision date 20-May-2022

The Water Environment (Water Framework Directive) (England and Wales) Regulations 2017 (as amended)

Not applicable

Poisons Act 1972 (Explosive Precursors) Regulations (as Amended)

Not applicable

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

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

+ Sensitisers

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 Calculation method Serious eye damage/eye irritation 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

R8 Pastorex Meningitis N. meningitidis Y/W135 Latex

Revision date 20-May-2022

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

20-May-2022

World Health Organization

Revision date

Revision Note

Significant changes throughout SDS. Review all sections

This material safety data sheet complies with the requirements of UK REACH Regulations (SI 2019/758 as amended) 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

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



SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of: UK REACH Regulations (SI 2019/758 as amended)

The Junction

Station Road

UK

Watford, WD17 1ET

Revision date 20-May-2022 Revision Number 1

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

1.1. Product identifier

Product Name R6 Pastorex Meningitis N. meningitidis A Latex

Catalogue Number(s) 6178F, 12016498

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 Restricted to professional users In vitro diagnostic

Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

Corporate HeadquartersManufacturerLegal Entity / Contact AddressBio-Rad Laboratories Inc.Bio-RadBio-Rad Laboratories Ltd

Bio-Rad Laboratories Inc.

Bio-Rad

1000 Alfred Nobel Drive

Hercules, CA 94547

Bio-Rad

3 boulevard Raymond Poincaré

92430 Marnes-la-Coquette

USA France

e-mail: fds-msds.fr@bio-rad.com

Technical Service 00800 00246 723 Techsupport.UK@bio-rad.com

1.4. Emergency telephone number

For further information, please contact

24 Hour Emergency Phone Number CHEMTREC UK: 44-870-8200418

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Precautionary statements

P261 - Avoid breathing dust/fume/gas/mist/vapours/spray

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

P362 + P364 - Take off contaminated clothing and wash it before reuse

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

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

2.3. Other hazards

Contains animal source material. (Cattle). Harmful to aquatic life.

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Chemical name	Weight-%	EC No (EU Index No)	UK REACH registration number	Classification according to GB CLP (SI 2020/1567 as amended)	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Sucrose 57-50-1	2.5 - 5	200-334-9	-	-	-	-	-
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothi azolone 55965-84-9	0.001 - 0.01	(613-167-00-5)	-	Acute Tox. 3 (H311) Acute Tox. 3 (H331)	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

Full text of H- and EUH-phrases: see section 16

This product does not contain candidate substances of very high concern at a concentration >= 0.1% (UK 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.

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Revision date 20-May-2022

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 doctorsMay 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. Ensure adequate ventilation. Use personal

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

from and upwind of spill/leak.

6.2. Environmental precautions

Environmental precautions See Section 12 for additional Ecological Information.

6.3. Methods and material for containment and cleaning up

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

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

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

Revision date 20-May-2022

contaminated clothing and wash it before reuse.

General hygiene considerations Wash hands before breaks and immediately after handling the product.

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.

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	United Kingdom
Sucrose	TWA: 10 mg/m ³
57-50-1	STEL: 20 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)

No information available.

8.2. Exposure controls

Engineering controls No information available.

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.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state Liquid
Appearance Liquid
Colour blue
Odour Odourless.

Odour threshold No information available

<u>Property</u> <u>Values</u> <u>Remarks • Method</u>

Melting point / freezing pointNo data availableNone knownBoiling point / boiling rangeNo data availableNone knownFlammability (solid, gas)No 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 temperatureNone known

pHNone knownpH (as aqueous solution)No data availableNone knownKinematic viscosityNo data availableNone knownDynamic viscosityNo data availableNone known

Water solubility Miscible in water

Solubility(ies)No data availableNone knownPartition coefficientNo data availableNone knownVapour pressureNo data availableNone knownRelative densityNo data availableNone known

Bulk density
No data available
No data available

Vapour densityNo data availableNone known

Particle characteristics

Particle SizeNo information availableParticle Size DistributionNo information available

9.2. Other information

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

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Incompatible materialsNone 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. Toxicological information

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

Revision date 20-May-2022

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

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Sucrose	= 29700 mg/kg (Rat)	-	-
5-Chloro-2-methyl-3(2H)-isothia zolone, mixture with	= 53 mg/kg (Rat)	= 87.12 mg/kg(Rabbit)	-
2-methyl-3(2H)-isothiazolone			

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.

No information available. STOT - repeated exposure

Aspiration hazard No information available. Other adverse effects No information available.

SECTION 12: Ecological information

12.1. Toxicity

Harmful to aquatic life with long lasting effects. **Ecotoxicity**

Unknown aquatic toxicity Contains 0 % of components with unknown hazards to the aquatic environment.

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	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

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

12.6. Endocrine disrupting properties

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

R6 Pastorex Meningitis N. meningitidis A Latex

Revision date 20-May-2022

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
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 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 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

SECTION 15: Regulatory information

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

National regulations

Authorisations and/or restrictions on use:

This product does not contain substances subject to authorisation (UK REACH - Annex XIV). This product does not contain substances subject to restriction (UK REACH - Annex XVII).

Persistent Organic Pollutants

Not applicable

Export Notification requirements

Not applicable

Named dangerous substances per COMAH Regulations 2015 (as amended)

Not applicable

The Ozone-Depleting Substances Regulations 2015

Not applicable

The Biocidal Products Regulations 2001 (as amended)

Chemical name	The Biocidal Products Regulations 2001 (as amended)
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with	PT02 - Disinfectants and algaecides not intended for direct
2-methyl-3(2H)-isothiazolone - 55965-84-9	application to humans or animals

R6 Pastorex Meningitis N. meningitidis A Latex

PT06 - Preservatives for products during storage
PT13 - Working or cutting fluid preservatives
PT04 - Food and feed area
PT11 - Preservatives for liquid-cooling and processing
systems
PT12 - Slimicides

Revision date 20-May-2022

The Water Environment (Water Framework Directive) (England and Wales) Regulations 2017 (as amended) Not applicable

Poisons Act 1972 (Explosive Precursors) Regulations (as Amended)

Not applicable

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

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

+ Sensitisers

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 Calculation method Serious eye damage/eye irritation 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

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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 date

20-May-2022

Revision Note

Significant changes throughout SDS. Review all sections

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End of Safety Data Sheet



SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of: UK REACH Regulations (SI 2019/758 as amended)

The Junction

Station Road

UK

Watford, WD17 1ET

Revision date 20-May-2022 Revision Number 1

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

1.1. Product identifier

Product Name R7 Pastorex Meningitis N. meningitidis C Latex

Catalogue Number(s) 6178G, 12016538

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 Restricted to professional users In vitro diagnostic

Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

Corporate HeadquartersManufacturerLegal Entity / Contact AddressBio-Rad Laboratories Inc.Bio-RadBio-Rad Laboratories Ltd

Bio-Rad Laboratories Inc.

Bio-Rad

1000 Alfred Nobel Drive

Hercules, CA 94547

Bio-Rad

3 boulevard Raymond Poincaré

92430 Marnes-la-Coquette

USA France

e-mail: fds-msds.fr@bio-rad.com

Technical Service 00800 00246 723

Techsupport.UK@bio-rad.com

1.4. Emergency telephone number

For further information, please contact

24 Hour Emergency Phone Number CHEMTREC UK: 44-870-8200418

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Precautionary statements

P261 - Avoid breathing dust/fume/gas/mist/vapours/spray

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

P362 + P364 - Take off contaminated clothing and wash it before reuse

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

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

2.3. Other hazards

Contains animal source material. (Cattle). Harmful to aquatic life.

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Chemical name	Weight-%	EC No (EU Index No)	UK REACH registration number	Classification according to GB CLP (SI 2020/1567 as amended)	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Sucrose 57-50-1	2.5 - 5	200-334-9	-	-	-	-	-
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothi azolone 55965-84-9	0.001 - 0.01	(613-167-00-5)	-	Acute Tox. 3 (H311) Acute Tox. 3 (H331)	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

Full text of H- and EUH-phrases: see section 16

This product does not contain candidate substances of very high concern at a concentration >= 0.1% (UK 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.

Wash with soap and water. May cause an allergic skin reaction. In the case of skin irritation Skin contact

or allergic reactions see a doctor.

Ingestion Rinse mouth.

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

Itching. Rashes. Hives. **Symptoms**

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.

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

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. Ensure adequate ventilation. Use personal

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

from and upwind of spill/leak.

For emergency responders Use personal protection recommended in Section 8.

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 Prevent further leakage or spillage if safe to do so.

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

Clean contaminated objects and areas thoroughly observing environmental regulations. Prevention of secondary hazards

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.

Wash hands before breaks and immediately after handling the product. General hygiene considerations

7.2. Conditions for safe storage, including any incompatibilities

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

product and label instructions.

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	United Kingdom
Sucrose	TWA: 10 mg/m ³
57-50-1	STEL: 20 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.

No information available. **Derived No Effect Level (DNEL)**

Predicted No Effect Concentration

(PNEC)

No information available.

8.2. Exposure controls

No information available. **Engineering 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.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state Liquid Liquid **Appearance** Colour red Odour Odourless.

Odour threshold No information available

Property Values Remarks • Method

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 No data available

limits

Lower flammability or explosive No data available

limits

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

pH (as aqueous solution) No data available None known Kinematic viscosity No data available None known Dynamic viscosity No data available 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 No data available Relative density None known

No data available **Bulk density 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

SECTION 10: Stability and reactivity

10.1. Reactivity

No information available. Reactivity

10.2. Chemical stability

Stability Stable under normal conditions.

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

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. Toxicological information

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

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Sucrose	= 29700 mg/kg (Rat)	-	-
5-Chloro-2-methyl-3(2H)-isothia zolone, mixture with	= 53 mg/kg (Rat)	= 87.12 mg/kg(Rabbit)	-
2-methyl-3(2H)-isothiazolone			

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

Skin corrosion/irritation No information available.

No information available. Serious eye damage/eye irritation

Respiratory or skin sensitisation May cause an allergic skin reaction.

No information available. Germ cell mutagenicity

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. Other adverse effects No information available.

SECTION 12: Ecological information

12.1. Toxicity

Harmful to aquatic life with long lasting effects. **Ecotoxicity**

Unknown aquatic toxicity Contains 0 % of components with unknown hazards to the aquatic environment.

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	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

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

12.6. Endocrine disrupting properties

No information available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues/unused

Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

products

Contaminated packaging Do not reuse empty containers.

SECTION 14: Transport information

IATA

R7 Pastorex Meningitis N. meningitidis C Latex

Revision date 20-May-2022

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 Not regulated 14.2 UN proper shipping name 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 Not regulated 14.2 UN proper shipping name 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

Authorisations and/or restrictions on use:

This product does not contain substances subject to authorisation (UK REACH - Annex XIV). This product does not contain substances subject to restriction (UK REACH - Annex XVII).

Persistent Organic Pollutants

Not applicable

Export Notification requirements

Not applicable

Named dangerous substances per COMAH Regulations 2015 (as amended)

Not applicable

The Ozone-Depleting Substances Regulations 2015

Not applicable

The Biocidal Products Regulations 2001 (as amended)

Chemical name	The Biocidal Products Regulations 2001 (as amended)
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with	PT02 - Disinfectants and algaecides not intended for direct
2-methyl-3(2H)-isothiazolone - 55965-84-9	application to humans or animals

R7 Pastorex Meningitis N. meningitidis C Latex

PT06 - Preservatives for products during storage
PT13 - Working or cutting fluid preservatives
PT04 - Food and feed area
PT11 - Preservatives for liquid-cooling and processing
systems
PT12 - Slimicides

Revision date 20-May-2022

The Water Environment (Water Framework Directive) (England and Wales) Regulations 2017 (as amended) Not applicable

Poisons Act 1972 (Explosive Precursors) Regulations (as Amended)

Not applicable

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

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

+ Sensitisers

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 Calculation method Serious eye damage/eye irritation 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

R7 Pastorex Meningitis N. meningitidis C Latex

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Revision date 20-May-2022

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 date

20-May-2022

Revision Note

Significant changes throughout SDS. Review all sections

This material safety data sheet complies with the requirements of UK REACH Regulations (SI 2019/758 as amended) 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

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



SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of: UK REACH Regulations (SI 2019/758 as amended)

Revision date 20-May-2022 Revision Number 1

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

1.1. Product identifier

Product Name R1 Pastorex Meningitis N.meningitidis B/E.coli K1 Latex

Catalogue Number(s) 6160B, 12016504

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 Restricted to professional users In vitro diagnostic

Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

Corporate HeadquartersManufacturerLegal Entity / Contact AddressBio-Rad Laboratories Inc.Bio-RadBio-Rad Laboratories Ltd

Bio-Rad Laboratories Inc.Bio-RadBio-Rad Laboratories1000 Alfred Nobel Drive3 boulevard Raymond PoincaréThe JunctionHercules, CA 9454792430 Marnes-la-CoquetteStation Road

USA France Watford, WD17 1ET

e-mail: fds-msds.fr@bio-rad.com UK For further information, please contact

Technical Service 00800 00246 723

Techsupport.UK@bio-rad.com

1.4. Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC UK: 44-870-8200418

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

XGHS / EN Page 91/100



Signal word Warning

Hazard statements

H317 - May cause an allergic skin reaction

H412 - Harmful to aquatic life with long lasting effects

Precautionary statements

P261 - Avoid breathing dust/fume/gas/mist/vapours/spray

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

P362 + P364 - Take off contaminated clothing and wash it before reuse

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

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

2.3. Other hazards

Contains animal source material. (Cattle). Harmful to aquatic life.

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Chemical name	Weight-%	EC No (EU Index No)	UK REACH registration number	Classification according to GB CLP (SI 2020/1567 as amended)	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Sucrose 57-50-1	2.5 - 5	200-334-9	-	-	-	-	-
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothi azolone 55965-84-9	0.001 - 0.01	(613-167-00-5)	-	Acute Tox. 3 (H311) Acute Tox. 3 (H331)	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

Full text of H- and EUH-phrases: see section 16

This product does not contain candidate substances of very high concern at a concentration >= 0.1% (UK 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.

Eve 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

Itching. Rashes. Hives. **Symptoms**

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

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

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

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.

Use personal protection recommended in Section 8. For emergency responders

6.2. Environmental precautions

Environmental precautions See Section 12 for additional Ecological Information.

6.3. Methods and material for containment and cleaning up

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

Methods for cleaning 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 sectionsSee 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. Ensure adequate ventilation. In case of insufficient ventilation, wear suitable respiratory equipment. Do not eat, drink or smoke when using this product. Take off

Revision date 20-May-2022

contaminated clothing and wash it before reuse.

General hygiene considerations Wash hands before breaks and immediately after handling the product.

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.

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	United Kingdom
Sucrose	TWA: 10 mg/m ³
57-50-1	STEL: 20 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 No inform

(PNEC)

No information available.

8.2. Exposure controls

Engineering controls No information available.

Personal protective equipment

atex

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

Hand protection Wear suitable 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.

Revision date 20-May-2022

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical stateLiquidAppearanceLiquidColourredOdourOdourless.

Odour threshold No information available

<u>Property</u> <u>Values</u> <u>Remarks • Method</u>

Melting point / freezing pointNo data availableNone knownBoiling point / boiling rangeNo data availableNone knownFlammability (solid, gas)No 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 known

Decomposition temperatureNone known

pH None known
pH (as aqueous solution) No data available None known
Kinematic viscosity No data available None known
Dynamic viscosity No data available None known

Dynamic viscosity
Water solubility
No data available
Miscible in water

Solubility(ies)No data availableNone knownPartition coefficientNo data availableNone knownVapour pressureNo data availableNone knownRelative densityNo data availableNone known

Bulk density

Liquid Density

No data available

No data available

Vapour density No data available None known

Particle characteristics

Particle SizeNo information availableParticle Size DistributionNo information available

9.2. Other information

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity No information available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Latex

Revision date 20-May-2022

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 materialsNone 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. Toxicological information

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

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Sucrose	= 29700 mg/kg (Rat)	-	-
5-Chloro-2-methyl-3(2H)-isothia	= 53 mg/kg (Rat)	= 87.12 mg/kg (Rabbit)	-
zolone, mixture with			
2-methyl-3(2H)-isothiazolone			

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.

Revision date 20-May-2022

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.

Other adverse effects No information available.

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity Harmful to aquatic life with long lasting effects.

Unknown aquatic toxicityContains 0 % of components with unknown hazards to the aquatic environment.

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation

Component Information

Component information			
Chemical name	Partition coefficient		
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

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

12.6. Endocrine disrupting properties

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
 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 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

<u>ADR</u>

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 Users

Special Provisions None

SECTION 15: Regulatory information

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

National regulations

Authorisations and/or restrictions on use:

This product does not contain substances subject to authorisation (UK REACH - Annex XIV). This product does not contain substances subject to restriction (UK REACH - Annex XVII).

Persistent Organic Pollutants

Not applicable

Export Notification requirements

Not applicable

Named dangerous substances per COMAH Regulations 2015 (as amended)

Not applicable

The Ozone-Depleting Substances Regulations 2015

Not applicable

The Biocidal Products Regulations 2001 (as amended)

Chemical name	The Biocidal Products Regulations 2001 (as amended)
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with	PT02 - Disinfectants and algaecides not intended for direct
2-methyl-3(2H)-isothiazolone - 55965-84-9	application to humans or animals
	PT06 - Preservatives for products during storage
	PT13 - Working or cutting fluid preservatives
	PT04 - Food and feed area
	PT11 - Preservatives for liquid-cooling and processing
	systems
	PT12 - Slimicides

The Water Environment (Water Framework Directive) (England and Wales) Regulations 2017 (as amended)

Not applicable

Poisons Act 1972 (Explosive Precursors) Regulations (as Amended)

Not applicable

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 eve 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 (time-weighted average) STEL (Short Term Exposure Limit) TWA STEL

Ceiling Maximum limit value Skin designation

Sensitisers

Classification procedure

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

Method Used Calculation method Acute oral toxicity 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

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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))

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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)

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Organisation for Economic Co-operation and Development High Production Volume Chemicals Programme

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World Health Organization

Revision date 20-May-2022

Revision Note

Significant changes throughout SDS. Review all sections

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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