

# KIT SAFETY DATA SHEET



**Kit Product Name** Pastorex Meningitis Streptococcus B

**Kit Catalogue Number(s)** 61613

**Revision date** 20-May-2022

## Kit Contents

Catalogue Number(s)	Product Name
6178E	R5 Pastorex Meningitis Streptococcus B Latex



# SAFETY DATA SHEET

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

Revision date 20-May-2022

Previous 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** R5 Pastorex Meningitis Streptococcus B Latex

**Catalogue Number(s)** 6178E

**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 Headquarters

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

#### Manufacturer

Bio-Rad  
3 boulevard Raymond Poincaré  
92430 Marnes-la-Coquette  
France  
e-mail: fds-msds.fr@bio-rad.com

#### Legal Entity / Contact Address

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

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

Bio-Rad Laboratories (Pty) Ltd.  
34 Bolton Road  
Parkwood, Johannesburg 2193  
South Africa

For further information, please contact

#### Technical Service

00800 00246 723  
Ireland: Techsupport.UK@bio-rad.com  
India: support.india@bio-rad.com  
South Africa: cdg\_techsupport\_eemea@bio-rad.com

### 1.4. Emergency telephone number

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

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

<b>Skin sensitization</b>	Category 1A - (H317)
<b>Chronic aquatic toxicity</b>	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 - EU (§28, 1272/2008)**

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

P273 - Avoid release to the environment

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

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

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

**2.3. Other hazards**

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

## SECTION 3: Composition/information on ingredients

**3.1 Substances**

Not applicable

**3.2 Mixtures**

Chemical name	Weight-%	REACH registration number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Sucrose 57-50-1	2.5 - 5	No data available	200-334-9	No data available	-	-	-
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone 55965-84-9	0.001 - 0.01	No data available	-	Acute Tox. 3 (H301) Acute Tox. 3 (H311) Acute Tox. 3 (H331) Skin Corr. 1B (H314) Eye Dam. 1 (H318) Skin Sens. 1A (H317) (EUH071) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	Eye Irrit. 2 :: 0.06%≤C<0.6% Skin Corr. 1C :: C≥0.6% Skin Irrit. 2 :: 0.06%≤C<0.6% Skin Sens. 1A :: C≥0.0015% Eye Dam. 1 :: C≥0.6%	100	100

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

**Acute Toxicity Estimate**

If LD50/LC50 data is not available or does not correspond to the classification category, then the appropriate conversion value from CLP Annex I, Table 3.1.2, is used to calculate the acute toxicity estimate (ATEmix) for classifying a mixture based on its components

Chemical name	Oral LD50 mg/kg	Dermal LD50 mg/kg	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Sucrose 57-50-1	29700	No data available	No data available	No data available	No data available
5-Chloro-2-methyl-3(2H)-i sothiazolone, mixture with 2-methyl-3(2H)-isothiazol one 55965-84-9	53	87.12	No data available	No data available	No data available

This product does not contain candidate substances of very high concern at a concentration  $\geq 0.1\%$  (Regulation (EC) No. 1907/2006 (REACH), Article 59)

## SECTION 4: First aid measures

**4.1. Description of first aid measures**

<b>General advice</b>	Show this safety data sheet to the doctor in attendance.
<b>Inhalation</b>	Remove to fresh air.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
<b>Skin contact</b>	Wash with soap and water. May cause an allergic skin reaction. In the case of skin irritation or allergic reactions see a physician.
<b>Ingestion</b>	Rinse mouth.

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

<b>Symptoms</b>	Itching. Rashes. Hives.
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**4.3. Indication of any immediate medical attention and special treatment needed**

<b>Note to physicians</b>	May cause sensitization in susceptible persons. Treat symptomatically.
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## SECTION 5: Firefighting measures

**5.1. Extinguishing media**

<b>Suitable Extinguishing Media</b>	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
<b>Large Fire</b>	CAUTION: Use of water spray when fighting fire may be inefficient.
<b>Unsuitable extinguishing media</b>	Do not scatter spilled material with high pressure water streams.

**5.2. Special hazards arising from the substance or mixture**

<b>Specific hazards arising from the chemical</b>	Product is or contains a sensitizer. May cause sensitization by skin contact.
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**5.3. Advice for firefighters**

**Special protective equipment and precautions for fire-fighters** Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

## 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.

**Methods for cleaning up** Take 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 before reuse.

**General hygiene considerations** Handle in accordance with good industrial hygiene and safety practice.

### 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	European Union	Austria	Belgium	Bulgaria	Croatia
Sucrose 57-50-1	-	-	TWA: 10 mg/m <sup>3</sup>	TWA: 10.0 mg/m <sup>3</sup>	TWA: 10 mg/m <sup>3</sup> STEL: 20 mg/m <sup>3</sup>
5-Chloro-2-methyl-3(2H)-i	-	TWA: 0.05 mg/m <sup>3</sup>	-	-	-

sothiazolone, mixture with 2-methyl-3(2H)-isothiazolone 55965-84-9		Skin sensitizer			
Chemical name	Cyprus	Czech Republic	Denmark	Estonia	Finland
Sucrose 57-50-1	-	-	-	TWA: 10 mg/m <sup>3</sup>	-
Chemical name	France	Germany	Germany MAK	Greece	Hungary
Sucrose 57-50-1	TWA: 10 mg/m <sup>3</sup>	-	-	-	-
Chemical name	Ireland	Italy	Italy REL	Latvia	Lithuania
Sucrose 57-50-1	TWA: 10 mg/m <sup>3</sup> STEL: 20 mg/m <sup>3</sup>	-	TWA: 10 mg/m <sup>3</sup>	TWA: 5 mg/m <sup>3</sup>	TWA: 10 mg/m <sup>3</sup>
Chemical name	Portugal	Romania	Slovakia	Slovenia	Spain
Sucrose 57-50-1	TWA: 10 mg/m <sup>3</sup>	-	-	-	TWA: 10 mg/m <sup>3</sup>
Chemical name	Sweden		Switzerland		United Kingdom
Sucrose 57-50-1	-		-		TWA: 10 mg/m <sup>3</sup> STEL: 20 mg/m <sup>3</sup>
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone 55965-84-9	-		TWA: 0.2 mg/m <sup>3</sup>		-

**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****Personal protective equipment**

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

**Hand protection** Wear suitable gloves.

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

**Respiratory protection** No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

**General hygiene considerations** Handle in accordance with good industrial hygiene and safety practice.

**Environmental exposure controls** No information available.

**SECTION 9: Physical and chemical properties****9.1. Information on basic physical and chemical properties**

**Physical state** Liquid  
**Appearance** Liquid  
**Colour** yellow  
**Odour** Characteristic.  
**Odour threshold** No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
Melting point / freezing point	No data available	None known
Boiling point / boiling range	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Flash point	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature		None known
pH		None known
pH (as aqueous solution)	No data available	No information available
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Water solubility	Miscible in water	
Solubility(ies)	No data available	None known
Partition coefficient	No data available	None known
Vapour pressure	No data available	None known
Relative density	No data available	None known
Bulk density	No data available	
Liquid Density	No data available	
Vapour density	No data available	None known
Particle characteristics		
Particle Size	No information available	
Particle Size Distribution	No information available	

**9.2. Other information****9.2.1. Information with regard to physical hazard classes**

Not applicable

**9.2.2. Other safety characteristics**

No information available

**SECTION 10: Stability and reactivity****10.1. Reactivity**

Reactivity	No information available.
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**10.2. Chemical stability**

Stability	Stable under normal conditions.
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**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.
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**10.4. Conditions to avoid**

Conditions to avoid	None known based on information supplied.
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**10.5. Incompatible materials**

Incompatible materials	None known based on information supplied.
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**10.6. Hazardous decomposition products**

Hazardous decomposition products	None known based on information supplied.
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**SECTION 11: Toxicological information****11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008****Information on likely routes of exposure****Product Information**

<b>Inhalation</b>	Specific test data for the substance or mixture is not available.
<b>Eye contact</b>	Specific test data for the substance or mixture is not available.
<b>Skin contact</b>	May cause sensitization 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).
<b>Ingestion</b>	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)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone	= 53 mg/kg ( Rat )	= 87.12 mg/kg ( Rabbit )	-

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

<b>Skin corrosion/irritation</b>	No information available.
<b>Serious eye damage/eye irritation</b>	No information available.
<b>Respiratory or skin sensitization</b>	May cause sensitization by skin contact.
<b>Germ cell mutagenicity</b>	No information available.
<b>Carcinogenicity</b>	No information available.
<b>Reproductive toxicity</b>	No information available.
<b>STOT - single exposure</b>	No information available.
<b>STOT - repeated exposure</b>	No information available.



Aspiration hazard No information available.

#### 11.2. Information on other hazards

##### 11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.

##### 11.2.2. Other information

Other adverse effects No information available.

### SECTION 12: Ecological information

#### 12.1. Toxicity

Ecotoxicity Harmful to aquatic life with long lasting effects.

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 There is no data for this product.

#### 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 2-methyl-3(2H)-isothiazolone	The substance is not PBT / vPvB

#### 12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

#### 12.7. Other adverse effects

No information available.

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

Waste from residues/unused products Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging Do not reuse empty containers.

### SECTION 14: Transport information

**IATA**

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

**IMDG**

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

**RID**

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

**ADR**

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

<b>SECTION 15: Regulatory information</b>
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**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****National regulations****France**

Occupational Illnesses (R-463-3, France)

**European Union**

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

**Authorizations and/or restrictions on use:**

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

**Persistent Organic Pollutants**

Not applicable

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

Not applicable

**Plant protection products directive (91/414/EEC)**

Chemical name	Plant protection products directive (91/414/EEC)
Sucrose - 57-50-1	Plant protection agent

**EU - Biocides****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

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Skin designation

Classification procedure	
Classification according to Regulation (EC) No. 1272/2008 [CLP]	Method Used
Acute oral toxicity	Calculation method
Acute dermal toxicity	Calculation method
Acute inhalation toxicity - gas	Calculation method
Acute inhalation toxicity - Vapour	Calculation method
Acute inhalation toxicity - dust/mist	Calculation method
Skin corrosion/irritation	Calculation method
Serious eye damage/eye irritation	Calculation method
Respiratory sensitisation	Calculation method
Skin sensitisation	Calculation method
Mutagenicity	Calculation method
Carcinogenicity	Calculation method
Reproductive toxicity	Calculation method
STOT - single exposure	Calculation method
STOT - repeated exposure	Calculation method
Acute aquatic toxicity	Calculation method
Chronic aquatic toxicity	Calculation method
Aspiration hazard	Calculation method
Ozone	Calculation method

**Key literature references and sources for data used to compile the SDS**

Agency for Toxic Substances and Disease Registry (ATSDR)  
U.S. Environmental Protection Agency ChemView Database  
European Food Safety Authority (EFSA)  
European Chemicals Agency (ECHA) Committee for Risk Assessment (ECHA\_RAC)  
European Chemicals Agency (ECHA) (ECHA\_API)  
EPA (Environmental Protection Agency)  
Acute Exposure Guideline Level(s) (AELGL(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)  
Australia 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)  
Organization for Economic Co-operation and Development Environment, Health, and Safety Publications  
Organization for Economic Co-operation and Development High Production Volume Chemicals Program  
Organization for Economic Co-operation and Development Screening Information Data Set  
World Health Organization

**Revision Note** Significant changes throughout SDS. Review all sections

**Revision date** 20-May-2022

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

**Disclaimer**

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

**End of Safety Data Sheet**