KIT SAFETY DATA SHEET



Kit Product Name Pastorex Meningitis H. influenzae b

Kit Catalogue Number(s) 61616

Revision date 20-May-2022

Kit Contents

Catalogue Number(s)	Product Name
6178C	R3 Pastorex Meningitis H. influenzae b Latex

KITE / BE Page 1/13



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 Previous Revision Number 1 20-May-2022 20-May-2022

revision date

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 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

Corporate Headquarters Manufacturer Bio-Rad Laboratories Inc. Bio-Rad

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

USA 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

00800 00246 723 **Technical Service**

> 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

Page 2/13

Revision date 20-May-2022

Regulation (EC) No 1272/2008

Skin sensitization	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 - 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	-	-	-
Sodium chloride 7647-14-5	0.3 - 0.999	No data available	231-598-3	No data available	-	-	-
Glycine 56-40-6	0.3 - 0.999	No data available	200-272-2	No data available	-	-	-
5-Chloro-2-methyl-3 (2H)-isothiazolone, mixture with 2-methyl-3(2H)-isoth iazolone 55965-84-9	0.099	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	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%		100

	(H410)	Eye Dam. 1 ::	
		C>=0.6%	

Revision date 20-May-2022

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	Dermal LD50	Inhalation LC50 - 4	Inhalation LC50 - 4	Inhalation LC50 - 4
	mg/kg	mg/kg	hour - dust/mist - mg/L	hour - vapor - mg/L	hour - gas - ppm
Sucrose	29700	No data available	No data available	No data available	No data available
57-50-1					
Sodium chloride 7647-14-5	3000	10000	No data available	No data available	No data available
Glycine 56-40-6	7930	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		87.12	No data available	No data available	No data available

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

SECTION 4: First aid measures

4.1. Description of first aid measures

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

Inhalation Remove to fresh air.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids.

Consult a physician.

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

or allergic reactions see a physician.

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 physicians May cause sensitization 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.

Revision date 20-May-2022

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 sensitizer. May cause sensitization 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.

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

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

6.4. Reference to other sections

See section 8 for more information. See section 13 for more information. Reference to other sections

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	Bu	Igaria	Croatia
Sucrose	-		-	TWA: 10 mg/m ³		0.0 mg/m ³	TWA: 10 mg/m ³
57-50-1						3	STEL: 20 mg/m ³
5-Chloro-2-methyl-3(2H)-i	-		TWA: 0.05 mg/m ³	-		-	-
sothiazolone, mixture			Skin sensitizer				
with							
2-methyl-3(2H)-isothiazol							
one							
55965-84-9							
Chemical name	Cypri	JS	Czech Republic	Denmark	Es	stonia	Finland
Sucrose	-		-	-	TWA:	10 mg/m³	-
57-50-1							
Chemical name	Franc		Germany	Germany MAK	Gı	eece	Hungary
Sucrose	TWA: 10	mg/m³	-	-		-	-
57-50-1							
Chemical name	Irelar	-	Italy	Italy REL	Latvia		Lithuania
Sucrose	TWA: 10		-	TWA: 10 mg/m ³	: 10 mg/m³	5 mg/m ³	TWA: 10 mg/m ³
57-50-1	STEL: 20	mg/m³					
Sodium chloride	-		-	-	TWA:	5 mg/m ³	TWA: 5 mg/m ³
7647-14-5							
Glycine	-		-	-	TWA:	5 mg/m ³	-
56-40-6							
Chemical name	Portug		Romania	Slovakia	Slo	venia	Spain
Sucrose	TWA: 10	mg/m³	-	-		-	TWA: 10 mg/m ³
57-50-1							
Chemical name		Sweden		Switzerland			ted Kingdom
Sucrose			-	-			'A: 10 mg/m ³
57-50-1						STE	EL: 20 mg/m ³
	5-Chloro-2-methyl-3(2H)-isothia		-	TWA: 0.2 mg/m	1 ³		-
zolone, mixture with							
2-methyl-3(2H)-isothiazo	olone						
55965-84-9							

Biological occupational exposure limits

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies.

Derived No Effect Level (DNEL)
Predicted No Effect Concentration
(PNEC)

No information available. 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 protectionNo 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 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

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 No information available

Kinematic viscosity No data available None known No data available **Dynamic viscosity** None known

Miscible in water Water solubility

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

No data available **Bulk density Liquid Density** No data available

No data available Vapour density 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

No information available. Reactivity

10.2. Chemical stability

Stable under normal conditions. Stability

Explosion data

Sensitivity to mechanical impact None. Sensitivity to static discharge

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions None under normal processing.

10.4. Conditions to avoid

Conditions to avoidNone known based on information supplied.

10.5. Incompatible materials

Incompatible materials None known based on information supplied.

10.6. Hazardous decomposition products

Hazardous decomposition products None known based on information supplied.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of exposure

Product Information

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

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

Skin contact May cause 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

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)	-	-
Sodium chloride	= 3 g/kg (Rat)	> 10000 mg/kg (Rabbit)	> 42 mg/L (Rat)1 h
Glycine	= 7930 mg/kg (Rat)	-	-
5-Chloro-2-methyl-3(2H)-isothia zolone, mixture with 2-methyl-3(2H)-isothiazolone	= 53 mg/kg(Rat)	= 87.12 mg/kg (Rabbit)	-

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

Skin corrosion/irritationNo information available.

Serious eye damage/eye irritation No information available.

Respiratory or skin sensitization May cause an allergic skin reaction.

Revision date 20-May-2022

Germ cell mutagenicity No information available.

No information available. Carcinogenicity

Reproductive toxicity No information available.

STOT - single exposure No information available.

STOT - repeated exposure No information available.

No information available. **Aspiration hazard**

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.

11.2.2. Other information

No information available. Other adverse effects

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity Harmful to aquatic life with long lasting effects.

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

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Sodium chloride	-	LC50: 4747 - 7824mg/L (96h, Oncorhynchus mykiss) LC50: 5560 - 6080mg/L (96h, Lepomis macrochirus) LC50: 6020 - 7070mg/L (96h, Pimephales promelas) LC50: 6420 - 6700mg/L (96h, Pimephales promelas) LC50: =12946mg/L (96h, Lepomis macrochirus) LC50: =7050mg/L (96h, Pimephales promelas)	-	EC50: 340.7 - 469.2mg/L (48h, Daphnia magna) EC50: =1000mg/L (48h, Daphnia magna)
Glycine	_	LC50: >1000mg/L (96h, Oryzias latipes)	-	_

12.2. Persistence and degradability

Persistence and degradability No information available. Revision date 20-May-2022

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

Chemical name	PBT and vPvB assessment
Sodium chloride	The substance is not PBT / vPvB PBT assessment does
	not apply
Glycine	The substance is not PBT / vPvB
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

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

Revision date 20-May-2022

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

<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

France

Occupational Illnesses (R-463-3, France)

Chemical name	French RG number	Title
Sodium chloride	RG 78	-
7647-14-5		

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)

1 idili protoction producto directive (61, 11 i/226)	
Chemical name	Plant protection products directive (91/414/EEC)
Sucrose - 57-50-1	Plant protection agent
Sodium chloride - 7647-14-5	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 * Skin designation

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

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

Agency for Toxic Substances and Disease Registry (ATSDR)

U.S. Environmental Protection Agency ChemView Database

European Food Safety Authority (EFSA)

European Chemicals Agency (ECHA) Committee for Risk Assessment (ECHA_RAC)

European Chemicals Agency (ECHA) (ECHA_API)

EPA (Environmental Protection Agency)

Acute Exposure Guideline Level(s) (AEGL(s))

U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act

U.S. Environmental Protection Agency High Production Volume Chemicals

Food Research Journal

Hazardous Substance Database

International Uniform Chemical Information Database (IUCLID)

National Institute of Technology and Evaluation (NITE)

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)

Revision date 20-May-2022

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