KIT SAFETY DATA SHEET



Kit Product Name Pastorex Strep F Latex (60 Tests)

Kit Catalogue Number(s) 61733

Revision date 28-Jan-2025

Kit Contents

Catalogue Number(s)	Product Name
6121F	Pastorex Strep F Latex, 1 ml

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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 17-Dec-2024 Revision Number 1.3

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

1.1. Product identifier

Product Name Pastorex Strep F Latex, 1 ml

Catalogue Number(s) 6121F

Form Not applicable

Pure substance/mixture Mixture

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

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

Recommended use 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

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.

43 Bolton Road

Parkwood, Johannesburg 2192

South Africa

EU Representative:

Bio-Rad

3 bld Raymond Poincaré 92430 Marnes-la-Coquette

France

Phone: (33) 1-4795-6000

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

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CHEMTREC South Africa: 0-800-983-611

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to

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

Skin sensitisation	Category 1 - (H317)
Hazardous to the aquatic environment - chronic	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 and face protection

2.3. Other hazards

Contains animal source material. (Cattle).

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Chemical name	Weight-%	REACH registration	EC No (EU	Classification according	Specific	M-Factor	M-Factor
		number	Index No)	to Regulation (EC) No.	concentration		(long-term)
				1272/2008 [CLP]	limit (SCL)		
Sucrose	5 - 10	Not available	200-334-9	Not classified	-	-	-
57-50-1							
5-Chloro-2-methyl-3	0.001 -	Not available	(613-167-00	Acute Tox. 3 (H301)	Eye Irrit. 2 ::	100	100
(2H)-isothiazolone,	0.01		-5)	Acute Tox. 3 (H311)	0.06%<=C<0.6		
mixture with				Acute Tox. 3 (H331)	%		
2-methyl-3(2H)-isoth				Skin Corr. 1B (H314)	Skin Corr. 1C ::		
iazolone				Eye Dam. 1 (H318)	C>=0.6%		

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55965-84-9		Skin Sens. 1A (H317)	Skin Irrit. 2 ::	
		(EUH071)	0.06%<=C<0.6	
		Aquatic Acute 1 (H400)	%	
		Aquatic Chronic 1	Skin Sens. 1A	
		(H410)	:: C>=0.0015%	
			Eye Dam. 1 ::	
			C>=0.6%	

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

Acute Toxicity Estimate

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

Chemical name	Oral LD50 mg/kg		Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapour - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Sucrose 57-50-1	29700	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 doctor.

Skin contactWash 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.

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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.

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 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)

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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 Unior	Austria	Belgium	Bu	Igaria	Croatia
Sucrose 57-50-1	-	-	TWA: 10 mg/m ³	TWA: 1	0.0 mg/m ³	TWA: 10 mg/m ³ STEL: 20 mg/m ³
5-Chloro-2-methyl-3(2H)-i sothiazolone, mixture with 2-methyl-3(2H)-isothiazol one 55965-84-9	-	TWA: 0.05 mg/m ³ Sh+	-		-	-
Chemical name	Cyprus	Czech Republic	Denmark	Es	tonia	Finland
Sucrose 57-50-1	-	-	-	TWA:	10 mg/m ³	-
Chemical name	France	Germany TRGS	Germany DFG	Gr	eece	Hungary
Sucrose 57-50-1	TWA: 10 mg/m ³	-	-		-	-
Chemical name	Ireland	Italy MDLPS	Italy AIDII	La	atvia	Lithuania
Sucrose 57-50-1	TWA: 10 mg/m ³ STEL: 20 mg/m ³		TWA: 10 mg/m ³	TWA:	5 mg/m ³	TWA: 10 mg/m ³
Chemical name	Portugal	Romania	Slovakia	Slo	venia	Spain
Sucrose 57-50-1	TWA: 10 mg/m ³	-	-		-	TWA: 10 mg/m ³
Chemical name		Sweden	Switzerland			ited Kingdom
Sucrose 57-50-1		-	- TWA: 10 mg/r STEL: 20 mg/r			
5-Chloro-2-methyl-3(2H)-i zolone, mixture with 2-methyl-3(2H)-isothiazo 55965-84-9		-	TWA: 0.2 mg/m³ STEL: 0.4 mg/m³ S+		-	

Biological occupational exposure limits

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

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

No information available.

8.2. Exposure controls

Personal protective equipment

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

Hand protection Wear suitable gloves.

Skin and body protection Wear suitable protective clothing.

exceeded or irritation is experienced, ventilation and evacuation may be required.

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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 Suspension
Colour red
Odour Odourless.

Odour threshold No information available

Property Values Remarks • Method

Melting point / freezing pointNo data availableNone knownInitial boiling point and boiling rangeNo data availableNone knownFlammabilityNo 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** None known pН None known pH (as aqueous solution) No data available None known No data available Kinematic viscosity None known **Dynamic viscosity** No data available None known

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

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

Liquid Density

No data available

Relative vapour density

No data available

None known

Particle characteristics

Particle Size No information available Particle Size Distribution No information available

9.2. Other information

9.2.1. Information with regards to physical hazard classes

Not applicable

9.2.2. Other safety characteristics

No information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity No information available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

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

Information on likely routes of exposure

Product Information

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

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

Skin contact May cause sensitisation by skin contact. Specific test data for the substance or mixture is

not available. Repeated or prolonged skin contact may cause allergic reactions with

susceptible persons (based on components).

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

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms Itching. Rashes. Hives.

Acute toxicity

Numerical measures of toxicity

No information available

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.

Serious eye damage/eye irritation No information available.

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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.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties Not applicable.

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.

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)-isothiazolor	ne

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

Chemical name	PBT and vPvB assessment

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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

12.7. Other adverse effects

No information available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues/unused

Contaminated packaging

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

products

Do not reuse empty containers.

SECTION 14: Transport information

Λ	ıΛ

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 user

Special Provisions None

IMDG

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) 14.4 Packing group Not regulated 14.5 Environmental hazards Not applicable

14.6 Special precautions for user

Special Provisions None

according to IMO instruments

14.7 Maritime transport in bulk No information available

RID

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 user

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 user

Special Provisions None

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SECTION 15: Regulatory information

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

European Union

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

Authorisations and/or restrictions on use:

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

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

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) Regulation (EU) 2024/590

Not applicable

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

Chemical name	EU - Plant Protection Products (1107/2009/EC)
Sucrose - 57-50-1	Plant protection agent

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

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

<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 any hazard and/or precautionary statements referred to under Sections 2-15

EUH071 - Corrosive to the respiratory tract

H301 - Toxic if swallowed

H311 - Toxic in contact with skin

H314 - Causes severe skin burns and eye damage

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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 Sk* 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)

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)

U.S. National Toxicology Program (NTP)

New Zealand's Chemical Classification and Information Database (CCID)

Organisation for Economic Co-operation and Development Environment, Health, and Safety Publications

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

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

World Health Organization

Revision Note Significant changes throughout SDS. Review all sections.

Revision date 17-Dec-2024

Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH) Disclaimer

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

End of Safety Data Sheet

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