



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 15-Sep-2023

Revision Number 1.2

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

1.1. Product identifier

Product Name Exact Diagnostics Borrelia Run Control
Catalogue Number(s) BORRC
Nanoforms Not applicable
Pure substance/mixture Mixture

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

Recommended use 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

Exact Diagnostics
100 South Jones Street, Suite 100,
Fort Worth, Texas 76104
USA

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

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

2.2. Label elements

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

Hazard statements

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

EUH208 - Contains 5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone May produce an allergic reaction.

2.3. Other hazards

Contains human source material and / or potentially infectious components

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

| Chemical name | Weight-% | REACH registration number | EC No (EU Index No) | Classification according to Regulation (EC) No. 1272/2008 [CLP] | Specific concentration limit (SCL) | M-Factor | M-Factor (long-term) |
|--|--------------|---------------------------|---------------------|--|---|----------|----------------------|
| Trade secret | 20 - 35 | No data available | .? | No data available | - | - | - |
| Trade secret | 1 - 2.5 | No data available | .? | 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 | (613-167-00-5) | 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 - vapour - mg/L | Inhalation LC50 - 4 hour - gas - ppm |
|---|-----------------|-------------------|--|--|--|
| Trade secret | 29700 | No data available | No data available | No data available | No data available |
| Trade secret | 3000 | 10000 | Inhalation LC50 Rat >42 mg/L 1 h (no deaths occurred, aerosol, Source: ECHA_API) | >42 | Inhalation LC50 Rat >42 mg/L 1 h (no deaths occurred, aerosol, Source: ECHA_API) |
| 5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with | 53 | 87.12 | No data available | No data available | No data available |

| Chemical name | Oral LD50 mg/kg | Dermal LD50 mg/kg | Inhalation LC50 - 4 hour - dust/mist - mg/L | Inhalation LC50 - 4 hour - vapour - mg/L | Inhalation LC50 - 4 hour - gas - ppm |
|--|-----------------|-------------------|---|--|--------------------------------------|
| 2-methyl-3(2H)-isothiazolone 55965-84-9 | | | | | |

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

| | |
|---------------------|--|
| Inhalation | Remove to fresh air. |
| Eye contact | Contains human source material and / or potentially infectious components. Call a doctor. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. |
| Skin contact | Wash with soap and water. |
| Ingestion | Contains human source material and / or potentially infectious components. Call a doctor. |

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 | Contains human source material and / or potentially infectious components. |
|------------------------|--|

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 | 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

| | |
|-----------------------------|------------------------------|
| 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 Do not allow into any sewer, on the ground or into any body of water.

Methods for cleaning up Use: Disinfectant. Clean contaminated surface thoroughly.

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 Follow universal and standard precautions for handling potentially infectious materials.

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

| Chemical name | European Union | Austria | Belgium | Bulgaria | Croatia |
|--|---|------------------------------------|---------------------------|-----------------------------|---|
| Trade secret | - | - | TWA: 10 mg/m ³ | TWA: 10.0 mg/m ³ | TWA: 10 mg/m ³ STEL: 20 mg/m ³ |
| 5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone 55965-84-9 | - | TWA: 0.05 mg/m ³ Sh+ | - | - | - |
| Chemical name | Cyprus | Czech Republic | Denmark | Estonia | Finland |
| Trade secret | - | - | - | TWA: 10 mg/m ³ | - |
| Chemical name | France | Germany TRGS | Germany DFG | Greece | Hungary |
| Trade secret | TWA: 10 mg/m ³ | - | - | - | - |
| Chemical name | Ireland | Italy MDLPS | Italy AIDII | Latvia | Lithuania |
| Trade secret | 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 |
| Trade secret | - | - | - | TWA: 5 mg/m ³ | TWA: 5 mg/m ³ |

| Chemical name | Portugal | Romania | Slovakia | Slovenia | Spain |
|--|---------------------------|---------|---|----------|---|
| Trade secret | TWA: 10 mg/m ³ | - | - | - | TWA: 10 mg/m ³ |
| Chemical name | Sweden | | Switzerland | | United Kingdom |
| Trade secret | - | | - | | TWA: 10 mg/m ³ STEL: 20 mg/m ³ |
| 5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone 55965-84-9 | - | | S+ TWA: 0.2 mg/m ³ STEL: 0.4 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)

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 Follow universal and standard precautions for handling potentially infectious materials.

Environmental exposure controls No information available.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state Liquid
Colour clear
Odour No information available.
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 | 200 °C | |
| Decomposition temperature | | None known |
| pH | No data available | 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 | No data available | None known |
| 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 regards to physical hazard classes**

Not applicable

9.2.2. Other safety characteristics

No information available

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

Reactivity No information available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to mechanical impact None.

Sensitivity to static discharge None.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions 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. 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 | 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**

The following values are calculated based on chapter 3.1 of the GHS document
Component Information

| Chemical name | Oral LD50 | Dermal LD50 | Inhalation LC50 |
|--|-----------------------|--------------------------|-----------------------|
| Trade secret | = 29700 mg/kg (Rat) | - | - |
| Trade secret | = 3 g/kg (Rat) | > 10000 mg/kg (Rabbit) | > 42 mg/L (Rat) 1 h |
| 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

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.

Reproductive toxicity No information available.

STOT - single exposure No information available.

STOT - repeated exposure No information available.

Aspiration hazard No information available.

11.2. Information on other hazards**11.2.1. Endocrine disrupting properties**

Endocrine disrupting properties This product does not contain any known or suspected endocrine disruptors.

11.2.2. Other information

Other adverse effects No information available.

SECTION 12: Ecological information

12.1. Toxicity

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

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

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

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 2-methyl-3(2H)-isothiazolone | 0.7 |

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 |
|--|---------------------------------|
| Trade secret | The substance is not PBT / vPvB |
| 5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone | The substance is not PBT / vPvB |

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

| | |
|--|---|
| 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 |

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 |
|---------------|------------------|-------|
|---------------|------------------|-------|

| | | |
|--------------|-------|---|
| Trade secret | RG 78 | - |
|--------------|-------|---|

Germany

Water hazard class (WGK) slightly hazardous to water (WGK 1)

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

Persistent Organic Pollutants

Not applicable

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

Not applicable

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

| Chemical name | EU - Plant Protection Products (1107/2009/EC) |
|----------------|---|
| Trade secret - | Plant protection agent |
| Trade secret - | Plant protection agent |

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

| Chemical name | Biocidal Products Regulation (EU) No 528/2012 (BPR) |
|---|--|
| Trade secret - | Product-type 1: Human hygiene |
| 5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone - 55965-84-9 | Product-type 2: Disinfectants and algicides not intended 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 |

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)
Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
NIOSH (National Institute for Occupational Safety and Health)
National Library of Medicine's ChemID Plus (NLM CIP)
National Library of Medicine's PubMed database (NLM PUBMED)
National Toxicology Program (NTP)
New Zealand's Chemical Classification and Information Database (CCID)
Organisation for Economic Co-operation and Development Environment, Health, and Safety Publications
Organisation for Economic Co-operation and Development High Production Volume Chemicals Programme
Organisation for Economic Co-operation and Development Screening Information Data Set
World Health Organization

Revision Note Significant changes throughout SDS. Review all sections

Revision date 15-Sep-2023

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

Disclaimer

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

End of Safety Data Sheet