



SAFETY DATA SHEET

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

Revision date 18-Sep-2023

Revision Number 1.1

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

1.1. Product identifier

Product Name Exact Diagnostics CT/NG Positive Run Control

Catalogue Number(s) CTNGPOS

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

For further information, please contact

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

1.4. Emergency telephone number

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

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

2.2. Label elements

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

Hazard statements

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

2.3. Other hazards

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

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

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

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

SECTION 4: First aid measures

4.1. Description of first aid measures

| | |
|--------------|--|
| Inhalation | Remove to fresh air. |
| Eye contact | 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 | This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies. |
| Biological occupational exposure limits | This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies. |
| Derived No Effect Level (DNEL) | No information available. |
| Predicted No Effect Concentration (PNEC) | No information available. |

8.2. Exposure controls

| | |
|---|--|
| Engineering controls | No information available. |
| <u>Personal protective equipment</u> | |
| 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. |

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | |
|------------------------|---------------------------|
| Physical state | Liquid |
| Appearance | Clear |
| 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 | No data available | None known |
| Decomposition temperature | | None known |
| pH | 7.8-8.2 | |
| pH (as aqueous solution) | No data available | None known |
| Kinematic viscosity | No data available | None known |
| Dynamic viscosity | No data available | None known |
| Water solubility | 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

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 Avoid contact with metals. This product contains Sodium azide. Sodium azide can react with Copper, Brass, Lead, and solder in piping systems to form explosive compounds and toxic gases.

10.4. Conditions to avoid

Conditions to avoid None known based on information supplied.

10.5. Incompatible materials

Incompatible materials Metals.

10.6. Hazardous decomposition products

Hazardous decomposition products None known based on information supplied.

SECTION 11: Toxicological information**11.1. Toxicological information****Information on likely routes of exposure****Product Information**

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

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

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

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

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms No information available.

Acute toxicity**Numerical measures of toxicity****Delayed and immediate effects as well as chronic effects from short and long-term exposure**

Skin corrosion/irritation No information available.

Serious eye damage/eye irritation No information available.

Respiratory or skin sensitisation No information available.

| | |
|--------------------------|---------------------------|
| Germ cell mutagenicity | No information available. |
| Carcinogenicity | No information available. |
| Reproductive toxicity | No information available. |
| STOT - single exposure | No information available. |
| STOT - repeated exposure | No information available. |
| Aspiration hazard | No information available. |
| Other adverse effects | No information available. |

SECTION 12: Ecological information

12.1. Toxicity

| | |
|--------------------------|---|
| Ecotoxicity | 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. |

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 | No information available. |
|-------------------------|---------------------------|

12.6. Endocrine disrupting properties

No information available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

| | |
|-------------------------------------|---|
| Waste from residues/unused products | Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation. Flush pipes with water frequently if discarding solutions |
|-------------------------------------|---|

containing Sodium azide into metal piping systems.

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

Authorisations and/or restrictions on use:

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

Persistent Organic Pollutants

Not applicable

Export Notification requirements

Not applicable

Named dangerous substances per COMAH Regulations 2015 (as amended)

Not applicable

The Ozone-Depleting Substances Regulations 2015

Not applicable

The Biocidal Products Regulations 2001 (as amended)

Not applicable

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

Not applicable

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

Not applicable

International Inventories

Contact supplier for inventory compliance status

15.2. Chemical safety assessment**Chemical Safety Report**

No information available

SECTION 16: Other information**Key or legend to abbreviations and acronyms used in the safety data sheet****Legend**

SVHC: Substances of Very High Concern for Authorisation:

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

| | | | |
|---------|-----------------------------|------|----------------------------------|
| TWA | TWA (time-weighted average) | STEL | STEL (Short Term Exposure Limit) |
| Ceiling | Maximum limit value | * | Skin designation |
| + | Sensitisers | | |

Classification procedure

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

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

Agency for Toxic Substances and Disease Registry (ATSDR)
 U.S. Environmental Protection Agency ChemView Database
 European Food Safety Authority (EFSA)
 European Chemicals Agency (ECHA) Committee for Risk Assessment (ECHA_RAC)
 European Chemicals Agency (ECHA) (ECHA_API)
 EPA (Environmental Protection Agency)
 Acute Exposure Guideline Level(s) (AEGL(s))
 U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act
 U.S. Environmental Protection Agency High Production Volume Chemicals

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

Revision date 18-Sep-2023

Revision Note New Safety Data Sheet

This material safety data sheet complies with the requirements of UK REACH Regulations (SI 2019/758 as amended)
Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Disclaimer

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

End of Safety Data Sheet