



Multiplexed Diagnostics | Affordable Healthcare

SAFETY DATA SHEET (SDS) ACCORDING TO GHS AND CLP

SYNTHETIC POSITIVE CONTROLS

THIS PRODUCT IS CONSIDERED NON-HAZARDOUS. This product does not contain more than 1% of a component classified as hazardous and does not contain more than 0.1% of a component classified as carcinogenic in the GHS and CLP Regulation (EC) No 1272/2008. Therefore, per Global Harmonised Standards (GHS) ST/SG/AC.10/30/Rev.6, OSHA 29CFR1910.1200, Commonwealth of Australia [NOHSC: 1005, 1008(1999)], and the latest amendments to the Regulation (EC) No 1272/2008, this product does not require a Safety Data Sheet (SDS) or Material Safety Data Sheet (MSDS).

1.IDENTIFICATION OF SUBSTANCE/PREPARATION AND OF THE SUPPLIER.

1.1 PRODCT NAME

The product contains small amounts of synthetic DNA gene fragments in the form of frozen liquid, provided in a capped plastic tube. This SDS applies to all variations of Synthetic Positive Controls. The composition of the Synthetic Positive Control varies only in terms of the DNA sequence.

REF (Cat. No.)	Product Name
91011	Synthetic Positive Controls for Respiratory Pathogens
91021	Synthetic Positive Controls for STDs and Herpes
91031	Synthetic Positive Controls for Faecal Panels
91051	Synthetic Positive Controls for Bacteria and Bacterial Resistance
91071	Synthetic Positive Controls for Atypical Pneumonia
91081	Synthetic Positive Controls for CSF
91091	Synthetic Positive Controls for Fungal Panels
91171	Synthetic Positive Controls for Haemochromatosis
91191	Synthetic Positive Controls for HPV
91441	Synthetic Positive Controls for Sepsis

1.2 OTHER MEANS OF IDENTIFICATION

N/A

1.3 RECOMMENDED USE

Synthetic Positive Controls products are intended to be used as an accessory product with AusDiagnostics MT-PCR Systems.

1.4 TECHNICAL ENQUIRIES

For assistance or if any issues recur, please contact AusDiagnostics.

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2. HAZARDS IDENTIFICATION.

2.1 GHS CLASSIFICATION AND NATIONAL OR REGIONAL INFORMATION

THIS PRODUCT IS CONSIDERED NON-HAZARDOUS. Per OSHA 29CFR1910.1200, Commonwealth of Australia [NOHSC: 1005, 1008(1999)], and the latest amendments to the Regulation (EC) No 1272/2008, this product does not require a Material Safety Data Sheet (MSDS) or Safety Data Sheet (SDS).

This product does not contain more than 1% of a component classified as hazardous and does not contain more than 0.1% of a component classified as carcinogenic in GHS and Regulation (EC) No 1272/2008. Despite the classification of certain products/components as non-hazardous, we strongly recommend using prudent laboratory practices: avoiding unnecessary contact and use of personal protective equipment (PPE), which may include gloves, eye protection, and lab coats, during the use of any laboratory reagent.

AusDiagnostics shall not be held liable for any damages resulting from handling or from contact with the above product.

2.2 GHS LABEL ELEMENTS, INCLUDING PRECAUTIONARY STATEMENTS

- Pictogram: N/A
- Signal Word: N/A
- Hazard Statements: N/A
- Precautionary statements: N/A

2.3 OTHER HAZARDS

N/A

3. COMPOSITION/ INFORMATION ON INGREDIENTS

3.1 MIXTURES

Description, Synthetic DNA purified from pUC57 plasmid in E.coli.

Major Constituent, Deoxyribonucleic acid (DNA).

Synonyms, DNA primers, nucleic acid, DNA, deoxyribonucleic acid.

CAS #, None.

Dangerous Components, None.

Contains, C, H, N, O, P. May contain S.

4. FIRST AID MEASURES

4.1 DESCRIPTION OF NECESSARY MEASURES, ACCORDING TO DIFFERENT ROUTES OF EXPOSURE

- After Inhalation, Remove to fresh air. If irritation persists seek medical attention.
- After ingestion, do not induce vomiting. Wash mouth out with water, provided the person is conscious. Seek medical attention immediately.
- After Contact with Skin, Immediately wash with soap and copious amounts of water. If irritation is present get medical attention.
- After Contact with Eyes, Immediately flush eyes with copious amounts of water for several minutes. Consult a doctor immediately.

4.2 MOST IMPORTANT SYMPTOMS/EFFECTS, ACUTE AND DELAYED

May cause skin, eye and respiratory irritation.

To the best of our knowledge the symptoms/effects, acute and delayed of exposure to Synthetic Positive Controls have not been fully investigated, however skin contact, eye contact and ingestion should be avoided.

4.3 INDICATION OF IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENTS

There is no specific antidote. Treat symptomatically and supportively.

5. FIRE FIGHTING MEASURES

5.1 SUITABLE EXTINGUISHING MEDIA

Water spray, CO₂ or dry chemical powder. Large fires should be confronted with water spray or alcohol resistant foam.

5.2 SPECIFIC HAZARDS ARISING FROM THE CHEMICAL

No data is available for specific hazards of this product as a whole.

Specific Hazards, Emits toxic fumes under fire conditions.

5.3 FIRE FIGHTING PROTECTIVE MEASURES

Wear protective clothing to prevent contact with the skin and eyes.

Wear self contained breathing equipment to prevent inhalation of explosive or combustion gases.

6. ACCIDENTAL RELEASE MEASURES

6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

Wear appropriate protective clothing and chemically compatible gloves. Place spillage in appropriate container for waste disposal and ensure ventilation is adequate.

6.2 ENVIRONMENTAL PRECAUTIONS

Do not dispose to surface, ground water or sewers.

6.3 METHODS AND MATERIALS FOR CONTAMINATION AND CLEAN UP

Use a liquid-binding material (e.g. sand, sawdust, diatomite etc.) to absorb the spillage.

Place in closed containers for disposal. Ventilate area well after clean-up procedures have taken place.

Wear personal protection equipment (PPE) as outlined in Section 8.

Dispose of residue in accordance with federal, state, and local regulations.

7. HANDLING AND STORAGE

7.1 PRECAUTIONS FOR SAFE HANDLING

This product is only to be used by trained personnel in qualified laboratories. Observe all federal, state and local regulations. Avoid contact with eyes, skin and clothing. Avoid ingestion and inhalation. Wash thoroughly after handling. Use prudent laboratory practices for handling and storage of chemical substances of unknown toxicity.

7.2 CONDITIONS FOR SAFE STORAGE

This product must be stored at -20°C (see applicable product label and IFU).

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 CONTROL PARAMETERS, INGREDIENTS WITH EXPOSURE LIMIT VALUES

N/A.

8.2 ENGINEERING MEASURES

N/A (see section 7).

8.3 INDIVIDUAL PROTECTION MEASURES, PERSONAL PROTECTION EQUIPMENT

- Respiratory Protection, N/A.
- Hand Protection, Gloves should be worn, either rubber or chemical resistant.
- Eye Protection, Wearing safety goggles is advised, as is the availability of eye-wash stations.
- Skin Protection, Lab coats should be worn during handling. Safety deluge showers should be available. User must wear appropriate protective gloves to prevent contact with this material.
- Hygiene Practices, Avoid contact with skin or eyes, do not place in mouth.
Do not eat, drink or smoke when handling this product. Upon completion of the use of this product, dispose of protective gloves safely and wash hands thoroughly with soap and water.

9. PHYSICAL AND CHEMICAL PROPERTIES

Property	Details
Physical State	Frozen Liquid
Colour	Colourless
Odour	odourless
Melting point/freezing point	No data available
Boiling point/Boiling range	No data available
Flammability	No data available
Lower and upper explosion limit/ flammability limit	No data available
Flash point	No data available
Auto-ignition temperature	Product is not self-igniting
Decomposition temperature	No data available
pH	No data available
Kinematic viscosity	No data available
Solubility	Fully water soluble
Partition coefficient	No data available
Vapour pressure	No data available
Density and/or relative density	No data available
Relative vapour density	No data available

Particle characteristics	No data available
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10. STABILITY AND REACTIVITY

10.1 REACTIVITY

Dangerous Reactions, Avoid contact with strong oxidising agents.

Hazardous Decomposition Products, Carbon oxides, sulphur oxides.

10.2 CHEMICAL STABILITY

Product is stable under normal handling and storage conditions (below -20 °C, as per product label and IFU). Avoid excess heat, flame and pressure.

10.3 HAZARDOUS REACTIONS

Not known.

10.4 CONDITIONS TO AVOID

No dangerous reactions known if used according to specifications.

10.5 INCOMPATIBLE MATERIALS

Not known.

10.6 HAZARDUS DECOMPOSITION PRODUCTS

Not known.

11. TOXICOLOGICAL INFORMATION

Concise but complete and comprehensible description of the various toxicological (health) effects and the available data used to identify those effects.

11.1 INFORMATION ON THE LIKELY ROUTES OF EXPOSURE

- Inhalation, may be harmful if inhaled. May cause respiratory tract irritation.
- Skin, may be harmful if absorbed through skin, may causes skin irritation.
- Eyes, may cause eye irritation.
- Ingestion, may be harmful if swallowed.

11.2 SYMPTOMS RELATED TO THE CHEMICAL, PHYSICAL AND TOXICOLOGICAL PROPERTIES

To the best of our knowledge the chemical, physical and toxicological properties have not been fully investigated.

Acute Health Effects:	N/A
Chronic Health Effects:	This product does not contain any hazardous components above 1% or any carcinogens above 0.1% as defined in GHS and CLP.
Carcinogenic Effects:	N/A
Mutagenic Effects:	N/A
Teratogenic Effects:	N/A
Developmental Toxicity:	N/A
Hazards:	N/A

11.3 SIGNS AND SYMPTOMS OF EXPOSURE

- Acute toxicity, no data available.
- Irritation and corrosion, no data available.
- Sensitisation, no data available.
- Chronic exposure, no data available.

11.4 NUMERICAL MEASURES OF TOXICITY

No data available.

12. ECOLOGICAL INFORMATION

12.1 ECOTOXICITY EFFECTS

No data available.

12.2 ELIMINATION INFORMATION (PERSISTENCE AND DEGRADABILITY)

No data available.

12.3 BIOACCUMULATIVE POTENTIAL

No data available.

12.4 MOBILITY IN SOIL

No data available.

12.5 OTHER ADVERSE EFFECTS

No data available.

13. DISPOSAL CONSIDERATIONS

13.1 PRODUCT DISPOSAL

- Disposal must be made according to regional and national regulations.
- Must not be disposed together with household waste.
- Do not allow product to reach sewage system.

13.2 CONTAMINATED PACKAGING DISPOSAL

Contaminated packaging should be disposed of according to official regulations.

14. TRANSPORT INFORMATION

Shipment is made as a non-regulated material. No transportation restrictions apply.

The acute toxicity profile does not warrant shipment as a hazardous material (DOT) or a dangerous good (IATA).

14.1 UN NUMBER

N/A

14.2 UN PROPER SHIPPING NAME

- ADR / RID, Not hazardous good
- IMDG-Code / ICAO-TI / IATA-DGR, None

14.3 TRANSPORT HAZARD CLASS

Land, Maritime, and Air Transport, Not dangerous goods

14.4 PACKING GROUP

N/A

14.5 ENVIRONMENTAL HAZARDS

N/A

14.6 TRANSPORT IN BULK (ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE IBC CODE)

N/A

14.7 SPECIAL PRECAUTIONS FOR USER

N/A

15. REGULATORY INFORMATION

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

The toxicological properties of this material have not been investigated.

EU-Regulations, Regulation (EC) No 1272/2008

Labelling According to EU Guidelines

National regulations, Not determined

Other relevant regulations, Global Harmonised Standards (GHS)

16. DISCLAIMER

The information provided in this Safety Data Sheet (SDS) is accurate to the best of our present knowledge. However, this does not constitute a guarantee for any specific product features.

All substances and preparations may present unknown hazards and should be used with caution.

AusDiagnostics shall not be held liable for any damage resulting from the handling of or from contact with the above product. The information supplied in this SDS shall not establish a legally valid contractual relationship.

17. DOCUMENT HISTORY

Document ID of SDS	Date of Change	Changes
SDS-SPC-r08	01 Dec 2019	The format of the document have been changed, update contact details and a change of the document name.
SDS-SynthContr-r07	13 Feb 2018	Added mention of the CLP Regulation (Regulation (EC) No 1272/2008 which replace the current rules on classification, labelling and packaging of substances (Directive 67/548/EEC) and mixtures (Directive 1999/45/EC).
SDS-SynthContr-r06	4 Dec 2017	Manufacturer address updated
SDS-SynthContr-r05.1	3 Oct 2017	Minor correction - page 1; product description updated to 10 x 50 µl aliquot.
SDS-SynthContr-r05	28 Sept 2017	IMPORTANT: No new warnings or updates to safe use of product. Instrument name updated to <i>High-Plex 24 System</i> and <i>Ultra-Plex 48 system</i> consisting of MT Processor and MT Analyser. Product catalogue numbers updated to 5 digits. Product description updated to 10 x 50 µl aliquot.
SDS-SynthContr-r04	11 Nov 2016	IMPORTANT: No new warnings or updates to safe use of product. Changes made to comply with the GHS revision 6.

