

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 CLP Regulation (EC) No 1272/2008, this product does not require a Safety Data Sheet (SDS) or Material Safety Data Sheet (MSDS).

1. Identification Of The Substance Or Mixture And Of The Supplier

A) Product Name:

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

The product contains small amounts of frozen liquid synthetic DNA gene fragments provided in a capped plastic tube. This SDS applies to all variations of Synthetic Positive Controls: Each Synthetic Positive Control kit contains 10 tubes that contain 50 µL of frozen product. The composition of the Synthetic Positive Control varies only in terms of the DNA sequence.

B) Other means of identification:

N/A

C) Recommended use:

Products are for use with AusDiagnostics MT-PCR systems.

D) Supplier's details:

Contact in case of emergency:

Australian Office Working Hours (Monday-Friday: 8am to 6pm AEST)

AusDiagnostics Pty Ltd
290-292 Coward St, Mascot
NSW 2020
Tel: +61 (02) 9698 8030
Email: info@ausdiagnostics.com

UK Office Working Hours (Monday-Friday 9am to 5pm GMT/BST)

AusDiagnostics UK Ltd. UK
Unit 3,
Anglo Business Park, Asheridge Road,
Chesham, Bucks,
HP5 2QA
United Kingdom
Tel: +44 (0) 1494 300121

E) Emergency phone number:

See contact details above.

2. Hazards Identifications

A) GHS classification and any national or regional information:

This product is classified as 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, 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.

B) GHS label elements, including precautionary statements.

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

C) Other hazards:

None.

3. Composition/Information On Ingredients:

B) 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

A) Description of necessary measures, subdivided according to the different routes of exposure:

- After inhalation: remove to fresh air. If irritation persists consults a doctor immediately.
- After swallowing: Wash mouth out with water provided the person is conscious. Consult a doctor immediately.

- After contact with eyes: Immediately flush eye with copious amounts of water for several minutes. Consult a doctor immediately.
- After contact with skin: immediately wash with soap and copious amounts of water.

B) Most important symptoms/effects, acute and delayed:

May cause skin, eye and respiratory irritation.

To the best of our knowledge the symptoms/effects of exposure to synthetic DNA fragments have not been fully investigated.

C) Indication of immediate medical attention and special treatment needed, if necessary:

There is no specific antidote. Treat symptomatically and supportively.

5. Fire-Fighting Measures

A) Suitable (and unsuitable) extinguishing media:

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

B) Specific hazards arising from the chemical:

No data is available for specific hazards of this product as a whole. However, its composite chemicals have identified the following as specific hazards that may arise: Carbon oxides, nitrogen oxides (NO_x), Sulphur oxides, Hydrogen chloride gas, Potassium oxides, Magnesium oxide.

Specific Hazards: Emits toxic fumes under fire conditions.

C) Special protective equipment and precautions for fire-fighters

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. Specific Hazards: Emits toxic fumes under fire conditions.

6. Accidental Release Measures

A) Personal Precautions, protective equipment and emergency procedures:

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

B) Environmental Precautions:

Do not allow to enter the surface or ground water. Do not allow to enter sewers.

C) Methods and materials for containment 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

A) Precautions for safe Handling:

This product is only to be used by trained staff. 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.

B) Conditions for safe storage:

This product is stable when stored as directed (see applicable product label and IFU). *Store at -20°C.*

8. Exposure Controls/ Personal Protection

A) Control parameters - ingredients with exposure limit Values:

None

B) Engineering Measures:

None required, see section 7.

C) Individual protection measures - Personal Protective equipment:

- Respiratory Protection: None required.
- 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

- Physical properties appearance: Frozen liquid.
- Odour: odourless
- Melting point/melting range: No data available
- Boiling point/ boiling range: No data available
- Flammability: No data available
- Flash point: No data available
- Auto-flammability: Product is not self-igniting
- Igniting temperature: No data available
- Explosive Properties: No data available
- Decomposition temperature: No data available
- pH: No data available
- Relative Density: No data available
- Solubility in Water: Fully soluble

10. Stability And Reactivity

Hazardous Decomposition products:

A) Reactivity:

- Dangerous Reactions: Avoid contact with strong oxidising agents
- Hazardous Decomposition Products: Carbon oxides, sulphur oxides

B) Chemical Stability:

Product is stable under normal handling and storage conditions (see applicable product label and IFU). Avoid excess heat, flame and pressure.

C) Hazardous Reactions:

Carbon oxides, sulphur oxides

D) Conditions to avoid:

No dangerous reactions known if used according to specifications. Keep at -20 °C

E) Incompatible materials:

Not known

F) Hazardous 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, including:

A) 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 cause skin irritation
- Eyes: May cause eye irritation
- Ingestion: May be harmful if swallowed

B) 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

C) 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

D) Numerical measures of toxicity:

No data available

12. Ecological Information

A) Ecotoxicity effects:

No data available

B) Elimination information (persistence and degradability):

No data available

C) Bioaccumulative potential:

No data available

D) Mobility in soil:

No data available

E) Other adverse effects:

No data available

13. Disposal Considerations

A) Product Disposal

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

B) Contaminated Packaging Disposal:

Unclean packaging should be disposed of according to official regulations.

14. Transport Information

Ship 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).

A) UN number:

none

B) UN proper shipping name:

- ADR / RID: No hazardous good
- IMDG-Code / ICAO-TI / IATA-DGR: None

C) Transport hazard class:

Land, Maritime, and Air Transport: Not dangerous goods

D) Packing group:

None

E) Environmental hazards:

N/A

F) Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC code):

N/A

G) 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. Other Information

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

This document replaces the previous SDS for Synthetic Positive Control (Document ID: SDS-SynthContr-r06). See changes below.

Document ID of SDS	Date of Change	Changes
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.

END OF SDS