

SAFETY DATA SHEET

PlexPCR® Amplification Control

Issuing Date 23/11/2018

SECTION 1. IDENTIFICATION

1.1. Product Identifier

Product Name: PlexPCR® Amplification Control

Catalogue Number: 90002

1.2. Product Information

Intended Use: The *PlexPCR*® Amplification Control contains heterologous control DNA for use

as an amplification control in sample extracts and lysates.

Components: Amplification Control, Dilution Buffer

1.3. Recommended use and restrictions on use

Recommended Use: In vitro diagnostic (IVD)
Restrictions on Use: For professional users only

1.4. Details of the Supplier of the Safety Data Sheet

Manufacturer: SpeeDx Pty. Ltd.

Suite G16

National Innovation Centre Australian Technology Park

4 Cornwallis Street Eveleigh, NSW, 2015

Australia

Telephone: +61 (0)2 9209 4170

Authorized Representative: Medical Technology Promedt Consulting GmbH

Altenhofstrasse 80 66386 St. Ingbert

Germany

For further information, please contact:

Email: tech@speedx.com.au Website: www.speedx.com.au

1.5. Emergency telephone numbers

Emergency telephone: International: +61 (0)2 9209 4169 / For Australia: (02) 9209 4169

SECTION 2. HAZARDS IDENTIFICATION

2.1. GHS Classification

The product is a kit consisting of individual ingredients. The classification of the ingredients can be obtained from section 3. Section Label elements contains the resulting labelling for the kit.

2.2. GHS Label element

Not a hazardous substance or mixture.

2.3. Other hazards

No significant health effects are anticipated from routine use of this assay when following Universal Precautions and general safety laboratory practices. This kit is not considered hazardous as defined by the European Union (EU) Directives, Commonwealth of Australia (NOHSC), Occupational Safety and Health Administration (OSHA) or the Canadian Workplace Materials Information System (WHMIS)

It is recommended that all users of this kit take suitable precautions when working with this product or indeed any biochemical reagent. Such precautions may include personal protective equipment, such as a laboratory coat, gloves and eye protection. This also includes good laboratory hygiene practices to avoid any and all accidental exposure to workplace materials. Universal precautions should be followed when working with any potentially infectious material.



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SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Component Chemical Name CAS # EINECS # Concentration (%) Volume

SAFETY DATA SHEET (SDS) NOT REQUIRED FOR THIS KIT

The components of this kit are considered non-hazardous. The reagents contain <1% of a hazard classified component or <0.1% of a carcinogenic classified component, therefore, an SDS is not required in accordance with the following directives:

- European Union Directives 67/548/EC and 1999/45/EC
- Commonwealth of Australia [NOHSC:2011(2003) and NOHSC:1008(2004)]
- US Department of Labor OSHA 29CFR1910.1200
- Canadian Workplace Materials Information System WHMIS 2015

Other Information

Every effort has been made to adhere to the hazard criteria and content requirements of the U.S. OSHA Hazard Communication Standard, European Communities Safety Data Sheets Directive, Canadian Controlled Products Regulations, UK Chemical Hazard information and Packaging Regulations, and UN Globally Harmonized System of Classification and Labeling of Chemicals.

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It is expected that the user is a professional who is familiar with and follows generally accepted safe handling procedures. SpeeDx is not liable for any claims, losses, or damages of any individual or for lost profits or any special, indirect, incidental, consequential or exemplary damages of any kind, even if SpeeDx Pty. Ltd. has been advised of the possibility of such damages.

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