SAFETY DATA SHEET

ResistancePlus® GC

Issuing Date 06/09/2019

SECTION 1. IDENTIFICATION

1.1. Product Identifier

Product Name: ***ResistancePlus***® GC

Catalogue Number: 2011001 (ResistancePlus GC(610) 100 test)
2011025 (ResistancePlus GC(610) 25 test)
2013001 (ResistancePlus GC(550) 100 test)
2013025 (ResistancePlus GC(550) 25 test)

1.2. Product Information

Intended Use: The ***ResistancePlus***® GC gyrA product is an in vitro multiplexed qPCR test that detects Neisseria gonorrhoea and associated genetic resistance determinants and susceptibility markers to quinolones (ciprofloxacin), in a one well reaction.

Components: 20x GC+gyrA mix, 20x Control Mix 1 or 20x Control Mix 2, 2x ***Plex*** Mastermix, Nuclease Free Water

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.plexpcr.com

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.

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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