

SAFETY DATA SHEET

This SDS is applicable to all Conexio Genomics HLA SBT kits.

Prepared according to Regulation (EU) No. 1907 (2006)

Version: 8.0

Effective Date: 28th July 2016

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION

Product Name: **SBT Resolver™ (20 and 50 tests)**

Product Codes: XH-PD1.1-2(20), XH-PD1.1-2(50) (HLA-A)
BS-PD2.1-2(20), BS-PD2.1-2(50) (HLA-B)
HH-PD3.2-2(20), HH-PD3.2-2(50) (HLA-C)
HH-PD5.2-5(20), HH-PD5.2-5(50) (HLA-DRB1)
LG-PD5.2-7(20), LG-PD5.2-7(50) (HLA-DRB1)
PQ-PD6.2-2(20), PQ-PD6.2-2(50) (HLA-DQB1)
AN-PD6.2-3(20), AN-PD6.2-3(50) (HLA-DQB1)
HH-PD10.1(20), HH-PD10.1(50) (HLA-DPB1)
KD-PD10.2-1(20), KD-PD10.2-1(50) (HLA-DPB1)

Intended use (EU and Australia): In vitro diagnostic kit

COMPANY/UNDERTAKING IDENTIFICATION

Company Details: Conexio Genomics Pty Ltd
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2. HAZARD IDENTIFICATION

2.1 Classification of the substance or mixture

None of the substances or preparations contained in these kits is deemed to be hazardous according to EC Directive 67/548/EEC.

2.2 Label elements

None

3. COMPOSITION/INFORMATION ON INGREDIENTS

| Component | Substance | Concentration | Applicability | EC-No | CAS-No | EU classification |
|---------------------------|---|------------------------------|---|-----------|--|-------------------|
| PRE-PCR MIX | oligonucleotides | Various (<10pmol/μL each) | All | None | None | None |
| | dNTPs | <2.0mM | All | None | 365-08-2 1927-31-7 93919-41-6 102783-51-7 | None |
| | Magnesium chloride hexahydrate | <5mM | All except DQB1, DRB1 | 232-094-6 | 7791-18-6 | None |
| | Water | Not applicable | All | 231-791-2 | 7732-18-5 | None |
| | Ammonium sulphate | <50mM | HLA-A HLA-B | 231-984-1 | 7783-20-2 | None |
| | Tween 20 | <1% | HLA-A HLA-B | 500-018-3 | 9005-64-5 | None |
| | Tris (hydroxymethyl) aminomethane | <150mM | HLA-A HLA-B | 201-064-9 | 77-86-1 | Xi, R36/37/38 |
| | Glycerol | <10% | HLA-A HLA-B | None | 56-81-5 | None |
| | Hydrochloric acid | <1% | HLA-A HLA-B | 231-595-7 | 7647-01-0 | C, R34 - R37 |
| | Commercially prepared PCR Buffer [†] | Not available | HLA-C HLA-DPB1 HLA-DQB1 HLA-DRB1 | None | None | None |
| DNA POL | Taq polymerase | ≤5U/μL | All | None | None | None |
| SEQUENCING PRIMERS | oligonucleotides | Various (<20pmol/μL each) | All | None | None | None |

[†]The composition of the above kit components does not constitute a health or environmental hazard according to the European Union Directive 67/548/EEC, Commonwealth of Australia NOHSC: 1005 (1994) and 1008 (2004), and OSHA 29CFR 1910.1200.

4. FIRST AID MEASURES

Inhalation

Move affected individual(s) into fresh air.

Skin contact

Wash affected area(s) with soap and plenty of water.

Eye contact

Flush eye(s) with plenty of water, including under the eyelids.

Ingestion

Never give anything by mouth to an unconscious person. Rinse mouth with water.

In all instances, if symptoms persist consult a physician.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing agents:

Dry chemical, CO₂, water spray or regular foam.

Protective equipment:

For large fires, wear appropriate heat and flame resistant personal protective equipment and an approved self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Safe work practices:

If material is spilled, minimize exposure by using appropriate personal protective equipment as described in "Exposure Controls/Personal Protection". Where possible, stop spill from spreading further.

Environmental measures:

Prevent liquid from entering drains.

Cleaning measures:

Soak up with inert absorbent material.

Wash spill area with appropriate cleaning materials.

Dispose of spilled and contaminated material in accordance with appropriate national, state and local regulations.

7. HANDLING AND STORAGE

Handling

Store in original packaging, ensuring that the vials are tightly sealed.

Storage

Refer to packaging and Instructions for Use.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Substances with known occupational exposure limits: 56-81-5 glycerol and 7647-01-0 hydrochloric acid.

However the concentrations of these substances are well below their exposure limits.

General protective and hygienic measures:

Always maintain good housekeeping practices.

Ensure that food and beverages are not consumed in the immediate vicinity where these compounds are used.

Ensure hands are washed before and after handling kit components.

Breathing equipment:

Not required if work is conducted in a well-ventilated room.

Hand protection:

The use of laboratory gloves is required at all times. This measure not only prevents accidental exposure to the kit components, but also protects the samples being examined (i.e. genomic DNA contamination from user).

Eye protection:

The use of safety glasses is recommended.

Body protection:

The use of a laboratory coat or appropriate protective clothing is strongly recommended.

9. PHYSICAL AND CHEMICAL PROPERTIES

| | |
|---|---|
| Form: | liquid |
| Colour: | colourless |
| Odour: | odourless |
| Boiling point: | no data available |
| Melting point: | no data available: |
| Density: | no data available. |
| Auto-ignition: | products are NOT known to auto-ignite. |
| Danger of explosion: | products are NOT known to be explosive. |
| Solubility/miscibility with water: | fully soluble and miscible with water. |

10. STABILITY AND REACTIVITY

| | |
|--|---|
| Storage stability: | Kit components are stable under recommended storage conditions. Please refer to packaging and Instructions for Use. |
| Materials to avoid: | No known dangerous conditions to avoid when used according to specifications. |
| Hazardous decomposition products: | Not known. |

11. TOXICOLOGICAL INFORMATION

Primary toxicological effects of the final products:

| | |
|----------------------------------|------------------------------------|
| Acute toxicity: | No data available |
| Irritation and corrosion: | No irritant and corrosive effects. |
| Eye irritation: | No irritation effect |
| Sensitisation: | No sensitising effects are known. |

12. ECOLOGICAL INFORMATION

Ecological effects of the final products:

| | |
|---|--------------------|
| Elimination information (persistence and degradability): | No data available |
| Ecotoxicity effects: | No data available |
| Further information on ecology: | No data available. |

13. DISPOSAL CONSIDERATIONS

No specific disposal considerations are required. Dispose according to national, state and local regulations.

14. TRANSPORT INFORMATION

Products are transported by air with dry ice according IATA regulations.

15. REGULATORY INFORMATION

EU

The product does not require any hazard warnings according to European Community (EC) Directives.

US

SARA 313

These product are not regulated by SARA.

Clean Air Act, Section 112 Hazardous Air Pollutants (HAPs) (see 40 CFR 61)

These products do not contain any HAPs.

California Proposition 65

These products do not contain any chemicals listed under Proposition 65

16. OTHER INFORMATION

The information provided in this SDS is based on our present knowledge and is believed to be correct at the time of publication. Conexio Genomics Pty Ltd recommends that all kit components should be handled with caution in the event of unknown hazards.

The information provided here does not constitute a guarantee for any specific product, since Conexio Genomics Pty Ltd cannot control the conditions of use undertaken by the end user.

For further guidance contact:

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or your local distributor.

17. CHANGES TO FORMER ISSUED VERSION OF THIS SDS.

04/05/2011: Updated product codes for the HLA-DQB1 kits.

30/05/2011: Added details for HLA-DPB1; updated product name and codes; added new company logo.

16/11/2011: Minor typographical and grammatical changes. No changes to hazards, handling or storage conditions.

19/06/2013: Updated in relation to release of new SBT Resolver™ HLA-DRB1 kit (product codes HH-PD5.2-5 (20) and HH-PD5.2-5(50)). Previous version of kit (product codes HH-PD5.2-4(20) and HH-PD5.2-4(50) is discontinued.

22/03/2014: Updated manufacturer's address and contact details. Also "Intended Use" updated to include Australia.

16/04/2015: Updated in relation to release of new SBT Resolver™ HLA-DRB1, -DQB1 and -DPB1 kits (product codes LG-PD5.2-7, AN-PD6.2-3 and KD-PD10.2-1).

11/07/2016: Updated in relation to the change to commercially prepared PCR Buffer in AN-PD6.2-3 kits (HLA-DQB1). Changed MSDS to SDS.

28/07/2016: Updated manufacturer's address.

END