

SAFETY DATA SHEET

This SDS is applicable to all CareDx Pty Ltd HLA SBT kits.

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

Version: 1.0

Effective Date: 29th September 2017

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION

Product Name: **OLERUP SBT™ (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

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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.



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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. CareDx 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 CareDx 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.



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17. CHANGES TO FORMER ISSUED VERSION OF THIS SDS.

27-Sep-17: Version 1.0 drafted from version 8.0 of SDS for product under previous manufacturer and product name.

END