SAFETY DATA SHEET

First edition	Revision date	Replaces	Performed by	Page
28/11/2011, R01	04/09/2020, R09	25/03/2019, R08	Trossa AB/JW	1 of 9

Olerup SSP® Typing products

SECTION 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 PRODUCT IDENTIFIER

Olerup SSP® HLA Typing kits, KIR Genotyping kits, Wipe Test, Negative Control and DNA SizeMarker products.

1.2 RELEVANT IDENTIFIED USES OF THE SUBSTANCE OR MIXTURE AND USES ADVISED AGAINST

Olerup SSP® HLA Typing and KIR Genotyping Kits are qualitative in vitro diagnostic kits for the DNA typing of HLA Class I, HLA Class II alleles and KIR, respectively. The Negative Control, Wipe test and SizeMarker products are accessory products. The products are used by trained professionals in medical settings for the purpose of determining HLA phenotype. The source material tested is DNA.

1.3 DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET

CareDx AB
Franzéngatan 5, 112 51 Stockholm, Sweden
Tel: +46 8 50893900
If you have questions about the safety data sheet, please contact:
techsupport-labproducts@caredx.com

1.4 EMERGENCY TELEPHONE NUMBER

In emergency situations, EU: dial 112, USA and Canada: dial 911, Australia dial 000 or 112 and ask for Poison information.

SECTION 2. HAZARDS IDENTIFICATION

2.1 CLASSIFICATION OF THE SUBSTANCE OR MIXTURE (CLP)

Not classified according to the Regulation (EC) No 1272/2008 of the European parliament and of the council.

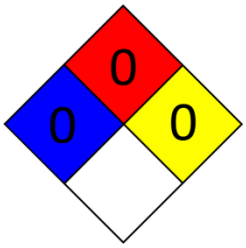
2.2 LABEL ELEMENTS

Labeling not required according to the Regulation (EC) No 1272/2008 of the European parliament and of the council.

Other labelling

EUH210 Safety data sheet available on request (due to the content of classified substances).

NFPA-rating may be used.



Other information

Based on available information, this mixture contains no substance meets the criteria for PBT or vPvB according to Annex XIII to Regulation (EC) No. 1907/2006 (REACH).

Do not contain any SVHC-substances (= Substance of Very High Concern) >= 0,1% from the Candidate list of EU.

2.3 OTHER HAZARDS

No other hazards are related to the product.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 MIXTURES

Description of the mixture

Tray and PCR Master Mix

Substances	EC No	CAS No	REACH No [2]	Conc weight %	CLP-classification [1]	
Trometamol (Tris-base) [a]	201-064-4	77-86-1	01-2119957659-16-xxxx	1%	Skin Irrit.2 Eye Irrit.2 STOT SE 3	H315 H319 H335
2-amino-2-(hydroxymethyl) propane-1,3-diol hydrochloride (Tris-HCl) [a]	214-684-5	1185-53-1	-	1%	Skin Irrit.2 Eye Irrit.2 STOT SE 3	H315 H319 H335

a) Classification according to one of the most used alternatives in ECHA´s Classification & Labelling Inventory.

The product also contains: Water, Oligonucleotides, Cresol Red, glycerol, Tween 20, potassium chloride, magnesium chloride, Taq DNA polymerase (only a component in kits including Taq). These substances are either not classified or are contained in such a low level that they do not need to be listed in the table above.

Other information

For a full text of H- phrases: See section 16.

SECTION 4. FIRST AID MEASURES

4.1 DESCRIPTION OF FIRST AID MEASURES

Inhalation

Fresh air and rest. Consult a doctor if symptoms occur.

Skin contact

Take off contaminated clothes. Rinse with water.

Eye contact

Rinse with soft jet of water or eye wash for several minutes. Use temperate water. Hold eyelids open, remove contact lenses. Consult a doctor if symptoms remain.

Ingestion

Rinse the mouth and drink water.

Information to medical advice

No specific information.

4.2 MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED

Inhalation: May cause discomfort in the respiratory tract.

Skin contact: Can cause mild transient irritation.

Eye contact: Causes transient irritation.

Ingestion: Smaller amounts are not expected to provide any acute or delayed symptoms.

4.3 INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

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SECTION 5. FIREFIGHTING MEASURES

5.1 EXTINGUISHING MEDIA RELEVANT

Suitable extinguishing media are water, carbon dioxide, dry chemical, or foam. Use the same extinguishing media as recommended for the surroundings. Do not use a water jet.

5.2 SPECIAL HAZARDS ARISING FROM THE SUBSTANCE MIXTURE

Combustible but not inflammable. In case of fire, toxic and corrosive fumes such as carbon- and nitrogen oxides, hydrogen chloride and hydrogen gas can form.

5.3 ADVICE FOR FIREFIGHTERS

Precautions according to standard procedures in the presence chemical fires. Use breathing apparatus to protect against toxic and corrosive gases and suitable protective clothing.

SECTION 6. ACCIDENTAL RELEASE MEASURES

6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

Avoid inhalation and contact with skin and eyes. Wear protective gloves and clothing and eye protection when cleaning the product. Keep unprotected persons away.

6.2 ENVIRONMENTAL PRECAUTIONS

Avoid discharge of large amounts into the sewer.

6.3 METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP

Absorb with a liquid binding material such as sand soil or similar. Collect and treat as conventional waste. Rinse away residues with plenty of water.

6.4 REFERENCE TO OTHER SECTIONS

See Section 8 for Exposure controls / personal protection and Section 13 for disposal considerations.

SECTION 7. HANDLING AND STORAGE

7.1 PRECAUTIONS FOR SAFE HANDLING

Avoid inhalation and direct contact with the product. Do not eat, drink and smoke when handling the product. Normal hand hygiene.

When handling the product, national regulations regarding chemical safety should apply.

7.2 CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

Store protected from light at temperature indicated on package.

7.3 SPECIFIC END USE

See section 1.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 OCCUPATIONAL EXPOSURE LIMIT VALUES

Contains no substances with occupational exposure limits in the working environment according to GESTIS International Limit Values http://limitvalue.ifa.dguv.de/.

8.2 EXPOSURE CONTROLS

Appropriate technical measures

Methods are developed to prevent direct contact. Ensure good ventilation. In case of insufficient ventilation, mechanical ventilation with local exhaust ventilation used.
Possibility to rinse eyes shall be available at place of work. Also, safety shower shall be available if handling large amounts.

Personal protection

Eye/face protection:	Wear eye protection if risk for splashing / eye contact.
Skin protection:	Use protective gloves when risk for direct. Recommended glove material: Nitrile.
Respiratory protection:	Not normally required.
Other protection:	Long coat.
Thermal hazard.	Irrelevant.

8.3 ENVIRONMENTAL EXPOSURE CONTROLS

Avoid excessive release to the environment if classified as hazardous.

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SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

Product description [3]

Appearance:	Tray: Red, dried in tray wells PCR Master Mix: Red, clear liquid
Odour:	None
pH:	8,3

Information about following is missing or is irrelevant: Odour threshold, melting-point, boiling-point, flash-point, evaporation rate, flammability, flammability or explosive limits, vapour pressure, vapour density, relative density, solubility in water and organic solvents, partition coefficient (Log Pow), auto-ignition temperature, decomposition temperature, viscosity, explosive and oxidizing properties.

9.2 OTHER INFORMATION

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SECTION 10. STABILITY AND REACTIVITY

10.1 REACTIVITY

The product is not reactive in normal handling and storage as recommended in section 7.

10.2 CHEMICAL STABILITY

The product is stable under normal handling and storage as recommended in section 7.

10.3 POSSIBILITY OF HAZARDOUS REACTIONS

None known.

10.4 CONDITIONS TO AVOID

High temperatures.

10.5 INCOMPATIBLE MATERIALS

Strong oxidizers and strong bases.

10.6 HAZARDOUS DECOMPOSITION PRODUCTS

No data.

SECTION 11. TOXICOLOGICAL INFORMATION

No toxicological data is available for the product; therefore, the evaluation is based on data for components. The product is not classified as hazardous to the health but contains small amounts of hazardous components. It is not expected to give any negative effects on health but should be handled according to good industrial practice.

11.1 INFORMATION ON TOXICOLOGICAL EFFECTS

Acute toxicity:	Not classified as acutely toxic.
Tris bas [4]	LD_{50} Oral: 5900 mg/kg (rat)
Potassium chloride [3]	LD_{50} Oral: 2600 mg/kg (rat) LD_{LO} Oral: 20 mg/kg (human)
Magnesium chloride hexahydrate [4]	LD_{50} Oral: 8100 mg/kg (rat)
Glycerol [3,4]	LD_{50} Oral: 4090 mg/kg (mouse) LD_{50} Oral: 12600 mg/kg (rat) LD_{50} Oral: 1428 mg/kg (human) LD_{50} Dermal: >10000 mg/kg (rabbit)
Corrosive/Irritating on the skin:	Not classified as irritant to skin but contain small amounts of substances which are classified.
Serious eye damage / irritation:	Not classified as an eye irritant but contain small amounts of substances which are classified, and splashes can cause pain and temporary irritation.
Respiratory / skin sensitization:	Not classified as a sensitizer.
Germ cell mutagenicity:	Not classified as mutagenic.
Carcinogenicity:	Not classified as a carcinogen.
Toxic to reproduction:	Not classified as toxic to reproduction.
Specific organ toxicity-single exposure:	Not classified with specific organ toxicity but contains small amounts of substances, which as dust may irritate mucous membranes in the respiratory tract.
Specific organ toxicity-repeated exposure:	No data.
Aspiration Hazard:	Not relevant.

Specific effects

None known.

11.2 OTHER INFORMATION

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SECTION 12. ECOLOGICAL INFORMATION

No toxicological data is available for the product; therefore, the evaluation is based on data for components. The product is not classified as a hazardous to the environment and is not expected to result in any negative environmental consequences but should be handled according to good industrial standards.

12.1 TOXICITY

Tris base is slightly toxic to water environment but is not classified and the amount in this product is very small. Glycerol has very low aquatic toxicity.

Tris bas [4]	IC_{50} Algae 72h: 0,2 mg/l

Glycerol [4]	LC_{50} Fish 96h: 67500 mg/l (species: Oncorhynchus mykiss) EC_{50} Daphnia 24h: >10000 mg/l (species: Daphnia magna) IC_{50} Algae 72h: 2900 mg/l

12.2 PERSISTENCE AND DEGRADABILITY

Contains glycerol which is easily biodegradable. No data on other constituents, but the amounts are small or very small.

Glycerol [4]	BOD5/COD = 1 63% is degraded in 14 days according to OECD-test 301C. 93% is degraded in 30 days according to OECD 301D-test (closed bottle).

12.3 BIOACCUMULATIVE POTENTIAL

Contains glycerol which has no potential for bioaccumulation. No data on other constituents, but the amounts are small or very small.

Glycerol [4]	BCF = 0,017 Log Pow = -1,76

12.4 MOBILITY IN SOIL

The product is water soluble.

12.5 RESULTS OF PBT AND vPvB ASSESSMENT

Based on available information, this mixture contains no substance meets the criteria for PBT or vPvB according to Annex XIII to Regulation (EC) No. 1907/2006 (REACH).

12.6 OTHER ADVERSE EFFECTS

None known.

SECTION 13. DISPOSAL CONSIDERATIONS

13.1 WASTE TREATMENT METHODS

Product

Classified as conventional waste according to the Commission Regulation (EU) No 1357/2014 on waste.
EWC-code: 18 01 07 (chemicals other than those mentioned in 18 01 06) according to the European Waste Catalogue.
All disposal practices must be in accordance with local, regional, national, and international regulations.

Packaging

Empty containers are treated as conventional waste and sent for recycling or incineration.

SECTION 14. TRANSPORT INFORMATION

This product is not covered by the regulations for transportation of dangerous goods.

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SECTION 15. REGULATORY INFORMATION

15.1 SAFETY, HEALTH AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE SUBSTANCE OR MIXTURE

This safety data sheet is prepared in accordance with the EUROPEAN PARLIAMENT AND COUNCIL REGULATION (EC) No 1907/2006 of 18 December 2006 concerning the registration, evaluation, authorization and restriction of chemicals (REACH) and Commission Regulation (EU) No 2015/830 of 28 May 2015 amending the European Parliament and Council Regulation (EC) No 1907/2006 on the registration, evaluation, authorization and restriction of chemicals (REACH).

Regulations

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (CLP).

GESTIS International Limit Values http://limitvalue.ifa.dguv.de/.

Commission Regulation (EU) No 1357/2014 of 18 December 2014 replacing Annex III to Directive 2008/98/EC of the European Parliament and of the Council on waste.

European Waste Catalogue (EWC-codes): http://www.sepa.org.uk/media/163421/ewc_guidance.pdf

15.2 CHEMICAL SAFETY ASSESSMENT

No Chemical Safety Assessment has been carried out for this mixture by the supplier.

SECTION 16. OTHER INFORMATION

Classification procedure

Test-data is prioritized at classification of the product. In absence of such, the classification-rules in the regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (CLP) been used.

Hazard statements in section 3

H315	Causes skin irritation.	H335	May cause respiratory irritation.
H319	Causes serious eye irritation.		

Abbreviations

BCF	Bio Concentration Factor
EC_{50}	Effective Concentration (= Concentration that shows effect in 50 % of the test subjects)
ECHA	European Chemical Agency
IC_{50}	Inhibitory Concentration (= Concentration that shows inhibition in 50 % of the test subjects)
LC_{50}	Lethal Concentration (= Concentration that would lead to 50 % deaths among the exposed test animals)
LD_{50}	Lethal Dose (= Dose that would lead to 50 % deaths among the exposed test animals)
LD_{LO}	Lethal Dose Low (= Lowest dose of a toxic material at which the death of the exposed test animal occurs.
Log Pow	Partition coefficient octanol - water
PBT	Persistent Bio-accumulative and Toxic substance
SVHC	Substance of Very High Concern
vPvB	very Persistent and very Bio-accumulative substance

Advice about education

To use this product, you should have an education that is relevant to the properties of the product and relevant use.

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References

1) Classification & Labelling Inventory Database, ECHA.
2) Registered substances, ECHA.
3) Information from older safety document: MSDS, version 28/11/2011.
4) Kemiska Ämnen online, Prevent.

Version description

This safety data sheet has been revised in accordance with title IV and annex II in the regulation (EC) No 1907/2006 of the European parliament and of the council (REACH).

Information has been modified under the following sections in the safety data sheet: 1 and 12.

The safety data sheet is dated 04/09/2020 and it replaces SDS version dated 25/03/2019.