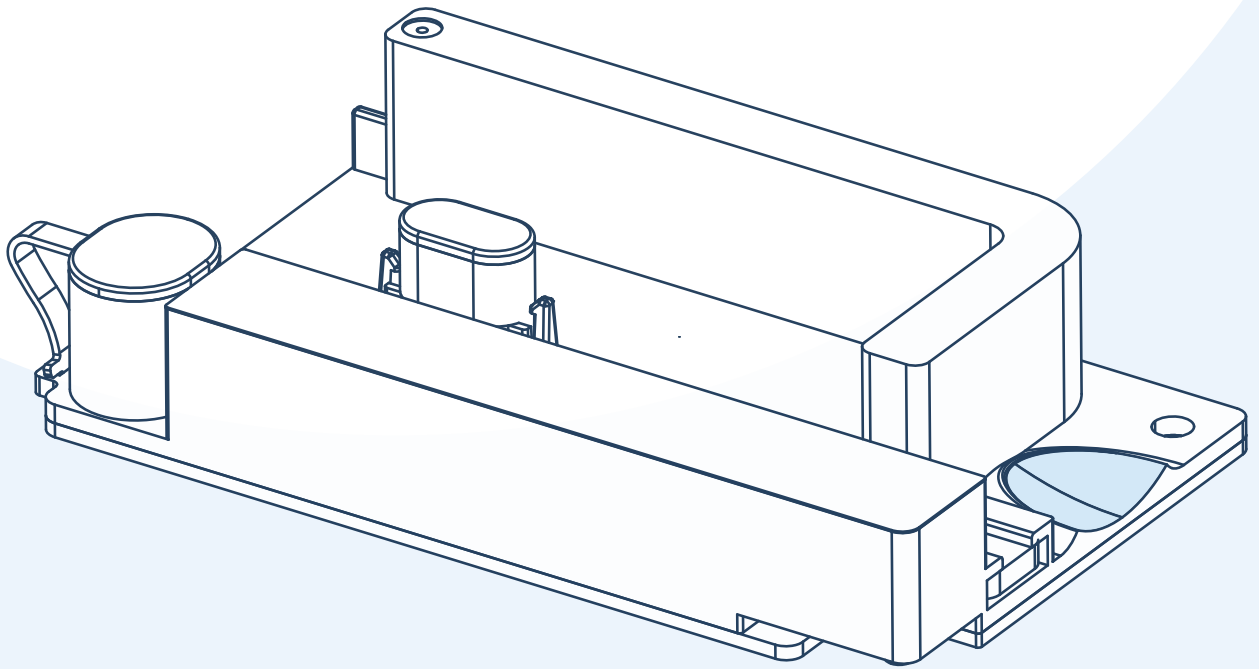


X8™ Genomic DNA Cartridge Kit

FOR USE WITH:

X8 OneTouch Instrument (Cat# X8-OT-101-IN)



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Safety Data Sheet prepared in accordance with SS 586 Part 3.

1. Identification

1.1. Product identifier

- Trade name. X8™ Genomic DNA Cartridge Kit.
- REACH Registration number. Not relevant.

1.2. Relevant identified uses of the substance or mixture and uses advised against.

- Product category. The X8 Genomic DNA Cartridge Kit rapidly automates genomic DNA (gDNA) extraction and purification from buffy coat, cell culture and bacterial sample types. The ready-to-use X8 Genomic DNA Cartridge Kit comes pre-filled with reagents, including proteinase K, thereby limiting the manual steps on the Xceler8 Platform to simply loading the sample into the cartridge.

1.3. Details of the supplier of the safety data sheet.

Manufacturer/Supplier

One BioMed Pte Ltd,
4 Fusionopolis Way,
Kinesis #06
Singapore 138635
tel. +65 8189 4412
Email. support@onebiomed.com

1.4. Emergency telephone number. +65 8189 4412

2. Hazard identification

2.1. Classification of the substance or mixture

- Classification according to Regulation (EC) No 1272/2008.
The product is not classified, according to the CLP regulation.

2.2. Label elements

- Labelling according to Regulation (EC) No 1272/2008. Non-Regulated Material.
- Hazard pictograms. Non-Regulated Material.
- Signal word. Non-Regulated Material.
- Hazard statements. Non-Regulated Material.
- Additional information. This value refers to knowledge of known, established toxicological or ecotoxicological values.
0% of the mixture consists of component(s) of unknown toxicity.

Contains 0% of components with unknown hazards to the aquatic environment.


2.3. **Other hazards.** None known

- **Results of PBT and vPvB assessment.**
 PBT. Not applicable.
 vPvB. Not applicable.

3. Composition/ information on ingredients

3.1. **Chemical characterisation.** Mixtures

- **Description.** Mixture of substances listed below with nonhazardous additions.

DANGEROUS COMPONENTS:		
1185-53-1	Tris Hydrochloride 	≤2.5%
	Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE3, H335	

- **Additional information.** For the wording of the listed hazard phrases refer to section 16.

4. First-aid measures

4.1. **Description of first aid measures**

- **General information.**
If symptoms persist, call a physician.
- **After inhalation.**
Supply fresh air; consult doctor in case of complaints.
- **After skin contact.**
Wash with soap and water. If skin irritation occurs, consult a doctor.
- **After eye contact.**
If eye irritation occurs, consult a doctor. Rinse opened eye for several minutes under running water.
- **After swallowing.**
Rinse mouth with water. If swallowed and symptoms occur, consult a doctor.

4.2. **Most important symptoms and effects, both acute and delayed.**
No further relevant information available.

4.3. **Indication of any immediate medical attention and special treatment needed.** No further relevant information available.

5. Fire-fighting measures

5.1. Extinguishing media.

- **Suitable extinguishing agents.**
Use fire extinguishing methods suitable to surrounding conditions.
- **For safety reasons unsuitable extinguishing agents.**
No further relevant information.
- **Special hazards arising from the substance or mixture.**
No further relevant information available.

5.2. Advice for firefighters.

- **Protective equipment.** As in any fire, wear self-contained breathing apparatus pressure-demand and full protective gear to prevent contact with skin and eyes.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures.

 Not required.

6.2. Environmental precautions.

 No special measures required.

6.3. Methods and material for containment and cleaning up.

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Dispose of the material collected according to regulations.

6.4. Reference to other sections.

- See Section 7 for information on safe handling.
- See Section 8 for information on personal protection equipment.
- See Section 13 for disposal information.

7. Handling & storage

7.1. Precautions for safe handling.

 No special precautions are necessary, if used correctly.

- **Information about fire and explosion protection.** No special measures required.

7.2. Conditions for safe storage, including any incompatibilities

Storage

- **Requirements to be met by storerooms and receptacles.** No special requirements.

- Information about storage in one common storage facility. Not required.
- Further information about storage conditions. None.

7.3. **Specific end use(s).** No further relevant information available.

8. Exposure controls / personal protection

8.1. Control parameters

- Additional information about design of technical facilities. No further data; see item 7.
- Ingredients with limit values that require monitoring at the workplace. The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- Additional information. The lists valid during the making were used as basis.

8.2. Exposure controls

- Personal protective equipment.
- General protective and hygienic measures. The usual precautionary measures are to be adhered to when handling chemicals. Wash hands before breaks and at the end of work.
- Respiratory protection. Not required.
- Protection of hands. Not required.
- Material of gloves. Not applicable.
- Penetration time of glove material. Not applicable.



- Eye protection. Goggles recommended during refilling.

8.3. **Environmental exposure controls.** None.

9. Physical & chemical properties

9.1. Information on basic physical and chemical properties

General Information

- Appearance
Form. Fluid.

Colour.	Clear.
• Odour.	Odourless.
• pH-value.	Not determined.
• Change in condition Melting point/freezing point.	Not determined.
• Flash point.	Not applicable.
• Flammability (solid, gas).	Not applicable.
• Ignition temperature.	Not applicable.
• Decomposition temperature.	Not determined.
• Auto-ignition temperature.	Product is not self-igniting.
• Explosive properties.	Product does not present an explosion hazard.
• Explosion limits Lower.	Not determined.
Upper.	Not determined.
• Vapour pressure.	Not determined.
• Density.	Not determined.
• Relative density.	Not determined.
• Vapour density.	Not determined.
• Evaporation rate.	Not determined.
• Solubility in / Miscibility with water.	Miscible.
• Partition coefficient. n-octanol/water.	Not determined.
• Viscosity. Dynamic.	Not determined.
Kinematic.	Not determined.
• Solvent content. VOC content.	0.00%
9.2. Other information.	No further relevant information available.

10. Stability & reactivity

- 10.1. **Reactivity.** No further relevant information available.
- 10.2. **Chemical stability.** Product is stable under normal conditions.
- **Thermal decomposition / conditions to be avoided.**
No decomposition if used according to specifications.
- 10.3. **Possibility of hazardous reactions.** No dangerous reactions known.
- 10.4. **Conditions to avoid.** No further relevant information available.
- 10.5. **Incompatible materials.** No further relevant information available.
- 10.6. **Hazardous decomposition products.** No dangerous decomposition products known.

11. Toxicological information

11.1. Information on toxicological effects

- **Acute toxicity.** Based on available data, the classification criteria are not met.
- **LD/LC50 values relevant for classification.** No data available.

Primary irritant effect

- **Skin corrosion/irritation.** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation.** Based on available data, the classification criteria are not met.
- **Sensitisation.** Based on available data, the classification criteria are not met.

Additional toxicological information.

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction).

- **Germ cell mutagenicity.** Based on available data, the classification criteria are not met.
- **Carcinogenicity.** Based on available data, the classification criteria are not met.
- **Reproductive toxicity.** Based on available data, the classification criteria are not met.
- **STOT (Specific target organ toxicity)-single exposure.** Based on

available data, the classification criteria are not met.

- **STOT (Specific target organ toxicity)-repeated exposure.** Based on available data, the classification criteria are not met.
- **Aspiration hazard.** Based on available data, the classification criteria are not met.

12. Ecological information

12.1. Toxicity

- **Aquatic toxicity.** No further relevant information available.

12.2. **Persistence and degradability.** No further relevant information available.

12.3. **Bioaccumulative potential.** No further relevant information available.

12.4. **Mobility in soil.** No further relevant information available.

- **Additional ecological information.**
- **General notes.** Not hazardous for water.

12.5. Results of PBT and vPvB assessment

- **PBT.** Not applicable.
- **vPvB.** Not applicable.

12.6. **Other adverse effects.** No further relevant information available.

13. Disposal considerations

13.1. Waste treatment methods

- **Recommendation.** Observe all federal, state and local environmental regulations when disposing of this material.

Uncleaned packaging

- **Recommendation.** Disposal must be made according to official regulations.

14. Transport information

14.1. UN-Number

- **ADR/ADN, IMDG, IATA** Non-Regulated Material.

14.2. UN proper shipping name

- ADR/ADN, IMDG, IATA Non-Regulated Material.
- 14.3. **Transport hazard class(es)**
- ADR/ADN, ADN, IMDG, IATA
 - Class. Non-Regulated Material.
- 14.4. **Packing group**
- ADR/ADN, IMDG, IATA Non-Regulated Material.
- 14.5. **Environmental hazards.** Not applicable.
- 14.6. **Special precautions for user** Not applicable.
- 14.7. **Transport in bulk according to Annex II of**
- Marpol and the IBC Code Not applicable.
 - UN "Model Regulation". Non-Regulated Material.

15. Regulatory information

15.1. **Safety, health and environmental regulations/legislation specific for the substance or mixture**

POISONS ACT - SCHEDULE 1
None of the ingredients are listed.

POISONS ACT - SCHEDULE 2, GROUP II
None of the ingredients are listed.

HEALTH PRODUCTS ACT - FIRST SCHEDULE- PSYCHOTROPIC SUBSTANCES
None of the ingredients are listed.

- Directive 2012/18/EU. Substance is not listed.
- Named dangerous substances - ANNEX I. None of the ingredients are listed.

LIST OF SUBSTANCES SUBJECT TO AUTHORISATION (ANNEX XIV)		
9002-93-1	Polyethylene glycol octylphenol ether	Sunset date: 2021-01-04

DIRECTIVE 2011/65/EU ON THE RESTRICTION OF THE USE OF CERTAIN HAZARDOUS SUBSTANCES IN ELECTRICAL AND ELECTRONIC EQUIPMENT – ANNEX II

None of the ingredients are listed.

- REGULATION (EU) 2019/1148

ANNEX I - RESTRICTED EXPLOSIVES PRECURSORS (UPPER LIMIT VALUE FOR THE PURPOSE OF LICENSING UNDER ARTICLE 5(3))

None of the ingredients are listed.

ANNEX II - REPORTABLE EXPLOSIVES PRECURSORS

None of the ingredients are listed.

REGULATION (EC) NO 273/2004 ON DRUG PRECURSORS

None of the ingredients are listed.

REGULATION (EC) NO 111/2005 LAYING DOWN RULES FOR THE MONITORING OF TRADE BETWEEN THE COMMUNITY AND THIRD COUNTRIES IN DRUG PRECURSORS

None of the ingredients are listed.

NATIONAL REGULATIONS:

The product is not subject to be labelled according with the prevailing version of the regulations on hazardous substances.

15.2. **Chemical safety assessment.** A Chemical Safety Assessment has not been carried out.

16. Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

16.1. Relevant phrases

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

16.2. Abbreviations and acronyms.

- ADR. Accord européen sur le transport des marchandises

dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road).

- **ADN.** The European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways.
- **IMDG.** International Maritime Code for Dangerous Goods.
- **IATA.** International Air Transport Association.
- **GHS.** Globally Harmonised System of Classification and Labelling of Chemicals.
- **EINECS.** European Inventory of Existing Commercial Chemical Substances.
- **ELINCS.** European List of Notified Chemical Substances.
- **CAS.** Chemical Abstracts Service (division of the American Chemical Society).
- **VOC.** Volatile Organic Compounds (USA, EU).
- **LC50.** Lethal concentration, 50 percent.
- **LD50.** Lethal dose, 50 percent.
- **PBT.** Persistent, Bioaccumulative and Toxic.
- **vPvB.** very Persistent and very Bioaccumulative.
- **Skin Irrit 2.** Skin corrosion/irritation – Category 2.
- **Eye Irrit 2.** Serious eye damage/eye irritation – Category 2.
- **STOT SE 3.** Specific target organ toxicity (single exposure) – Category 3.

*Data compared to the previous version altered.

Safety Data Sheet prepared in accordance with SS 586 Part 3.

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