

Safety Data Sheet

MDX158

Lyo-Ready Genotyping Direct qPCR Urine



Lyo-Ready Genotyping Direct qPCR Urine, 4x

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878 Date of original issue: 23/05/2023 Current revision: 23/05/2023 Version 1.0 Supersedes: None

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product form:	Mixture
Product name:	Lyo-Ready Genotyping Direct qPCR Urine, 4x
CAS No.:	N/A
EC No.:	N/A
REACH No.:	A registration number is not available for this substance as the substance or its uses are exempted from registration, the annual tonnage does not require a registration or the registration is envisaged for a later registration deadline.

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

Relevant identified uses:	Product for analytical use
Uses advised against:	Not described

1.3 Details of the supplier of the safety data sheet

Bioline Reagents Ltd, part of Meridian Bioscience	
Humber Road	Phone: +44 (0)20 8830 5300
London	Fax: +44 (0)20 8452 2822
NW2 6EW	E-mail: mbi.tech@meridianlifescience.com
United Kingdom	

1.4 Emergency telephone number

Emergency number:	+44 (0)1865 407 333 – English speaking (24 hours, 7 days)
Contact:	CareChem 24

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Lyo-Ready Genotyping Direct qPCR Urine, 4x

Classification according to Regulation (EC) No 1272/2008

Not a hazardous substance or mixture

2.2 Label elements

Lyo-Ready Genotyping Direct qPCR Urine, 4x

Labelling according Regulation (EC) No 1272/2008

Not a hazardous substance or mixture

Hazard Statements (CLP)	Precautionary Statements (CLP)
None	None

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2.3 Other hazards

Possible hazards from physicochemical properties:

Some hazards associated with individual components of this mixture are not relevant because the substances are present in concentrations below the GHS cut-off levels, change of physical state or because the mixture/ solution is buffered to pH 4-9 (see GHS Directive 1272/2008/EC Annex I, chapter 3.2.3.1.2.).

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

This substance/mixture contains no components considered to have endocrine disrupting effects or be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.1/3.2 Substance or Mixture

Lyo-Ready Genotyping Direct qPCR Urine, 4x

Name, synonyms and formulae	Product Identifier	Composition	Classification according to Regulation (EC) No. 1272/2008 (CLP)
N/A	N/A	N/A	N/A

This mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of REACH annex II

3.3 Remarks

List of H, EUR and P phrases: see section 16

SECTION 4: First aid measures

4.1 Description of first aid measures

First-aid measures general	If necessary consult a physician. Show this safety data sheet to the medical professional in attendance.
First-aid measures after inhalation	Remove to fresh air, keep the patient warm and provide resuscitation if necessary. If symptoms develop, obtain medical attention.
First-aid measures after skin contact	Remove contaminated clothing. Rinse the affected skin or mucous membrane thoroughly under running water. (If possible) use soap.
First-aid measures after eye contact	After contact with the eyes rinse thoroughly with plenty of water for at least 15 minutes with the eyelid wide open.
First-aid measures after ingestion	Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth and drink plenty of water.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling section 2.2 and/or in section 11

Not expected to present a significant hazard under anticipated conditions of normal use.

May cause slight irritation to eyes.

4.3 Indication of any immediate medical attention and special treatment needed

No additional recommendations.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Fire extinguishers appropriate to the fire classification, and, if applicable, a fire blanket must be available in a prominent location in the work area.

Suitable extinguishing media	All extinguishers like FOAM, WATER SPRAY, DRY POWDER, CARBON DIOXIDE can be used.
Unsuitable extinguishing media	None known.

5.2 Special hazards arising from the substance or mixture

Fire Hazard	Not flammable.
Hazardous decomposition products in case of fire	Carbon oxides, Nitrogen oxides, Hydrogen chloride gas, Phosphorus oxides, Lithium oxides, Potassium oxides, Sulphur oxides, Magnesium oxide.

5.3 Advice for firefighters

Firefighting instructions	Product package burns like paper or plastic. Spray any vapours released with water. Retain fire water where possible.
Protection during firefighting	Protective breathing apparatus, independent of the ambient air (isolated equipment), and sealed protective clothing is necessary in the event of large-scale formation of toxic substances.

5.4 Additional Information

None.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	Evacuate unnecessary personnel. Avoid breathing vapours, mist or gas. Avoid contact with skin, eyes and clothing. Regular staff training is necessary, indicating hazards and precautions on the basis of operating instructions. Restrictions on activity must be observed.
For emergency responders	Wear suitable protective equipment as defined in section 8.2 Prevent further leakage or spillage if safe to do so. Avoid release of materials into the environment.

6.2 Environmental precautions

Notify authorities if large amounts of the product enters sewers or public waters.

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6.3 Methods and material for containment and cleaning up

Small Scale release	<p>Make use of general chemical spill kit or other absorbent material.</p> <p>Clean any contaminated equipment and floors with plenty of water.</p> <p>Collect small amounts of leaked liquid and flush with copious amounts of water into drains.</p>
Large Scale release	<p>Bind any escaping liquid with inert absorbent material (sand, vermiculite or similar).</p> <p>Block/ prevent liquid entering any open drain.</p> <p>Collect contaminated materials and dispose in accordance to local regulations for the disposal of hazardous chemicals.</p>

6.4 Reference to other sections

SECTION 5.4: Additional fire precautions.

SECTION 8: Exposure controls/personal protection.

SECTION 13: Disposal considerations.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Precautions for safe handling	<p>Handling in accordance with the instructions supplied with the product.</p> <p>Provide adequate ventilation.</p> <p>Avoid breathing vapours, mist or gas.</p> <p>Avoid contact with skin, eyes and clothing.</p>
Hygiene measures	<p>Handle in accordance with good industrial hygiene and safety practice.</p> <p>Take off contaminated clothing and wash before reuse.</p> <p>Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.</p>

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions	<p>Keep only in the original container.</p> <p>Store in a cool well ventilated place out of direct sunlight.</p> <p>Keep container closed when not in use.</p>
Incompatible materials	<p>Store separately from: Bases, Oxidizing agents, Acids, Aluminium, Zinc.</p>

7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated.

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SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Lyo-Ready Genotyping Direct qPCR Urine, 4x		
United Kingdom	WEL TWA (mg/m ³)	N/A
United Kingdom	WEL TWA (ppm)	N/A
United Kingdom	WEL STEL (mg/m ³)	N/A
United Kingdom	WEL STEL (ppm)	N/A
United Kingdom	Remark (WEL)	Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Appropriate engineering controls:	Good ventilation or extraction system in the room, floor resistant to chemicals and washing facilities available.
General controls	Avoid all unnecessary exposure. Handle in accordance with good industrial hygiene and safety practice.
Respiratory protection	Respiratory protection not required. For nuisance exposures or if risk assessment requires, use type OV/AG (US) or type ABEK (EU EN 14387) respirator cartridges. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
Eye protection	Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN166 (EU) with integrated side shields or wrap-around protection.
Hand protection	Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Wear protective gloves that satisfy the specifications of EU Directive 89/686/EEC and the standard EN374 derived from it. Exact breakthrough times to be found through the manufacturer of the protective gloves and must be observed. Gloves should be removed and replaced if there are any signs of degradation or breakthrough. Splash contact – Material suggested Nitrile Rubber. Full contact – Material suggested Nitrile Rubber. If used in solution, or mixed with other substances, and under conditions which differ from EN374, contact the supplier of the CE approved gloves.
Skin and body protection	Long sleeved protective clothing.
Thermal protection	Not required for normal conditions of use.

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Other information	Eating, drinking, smoking, taking snuff and storage of food in work areas and at outdoor workplaces is prohibited. Avoid contact with the skin, eyes and clothing. Rinse any clothing on which the substance has been spilled, and soak it in water. Wash hands thoroughly with soap and water when stopping work and before eating.
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These recommendations are advisory only and must be evaluated by an industrial hygienist and safety officer familiar with the specific situation of anticipated use by our customers. It should not be construed as offering an approval for any specific use scenario.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Lyo-Ready Genotyping Direct qPCR Urine, 4x	
Physical state:	Dry
Colour:	White
Molecular Mass:	No data available
Odour:	Odourless
Odour threshold:	No data available
pH:	Not applicable
Relative evaporation rate (butylacetate=1):	No data available
Melting point:	No data available
Freezing point:	No data available
Boiling point or initial boiling point and boiling range:	No data available
Flash point:	No data available
Auto-ignition temperature:	No data available
Decomposition temperature:	No data available
Flammability (solid, liquid, gas):	Not applicable
Vapour pressure:	No data available
Relative vapour density at 20 °C:	No data available
Density and/or Relative density:	No data available
Solubility:	No data available
Log Pow:	No data available
Viscosity, kinematic:	No data available
Viscosity, dynamic:	No data available
Oxidising properties:	No data available
Explosive properties:	No data available
Explosive limits:	No data available

9.2 Other information

Data for the other parameters of the mixtures are not available, because no registration and no chemical safety report is required.

Relevant Properties of Substance Group: None

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SECTION 10: Stability and reactivity

10.1 Reactivity

Stable under normal conditions.

10.2 Chemical stability

Stable under recommended conditions.

10.3 Possibility of hazardous reactions

None known.

10.4 Conditions to avoid

Extremely high or low temperatures.

10.5 Incompatible materials

Bases, Oxidizing agents, Acids, Aluminium, Zinc.

10.6 Hazardous decomposition products

Hazardous decomposition products formed under fire conditions - Carbon oxides, Nitrogen oxides, Hydrogen chloride gas, Phosphorus oxides, Lithium oxides, Potassium oxides, Sulphur oxides, Magnesium oxide.

In the event of fire: see section 5

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Quantitative data on the toxicity of this product is not available.

Lyo-Ready Genotyping Direct qPCR Urine, 4x	
Acute toxicity	Not classified.
Additional information	Based on available data, the classification criteria are not met.
Skin corrosion/irritation	Not classified.
Additional information	Based on available data, the classification criteria are not met.
Serious eye damage/irritation	Not classified.
Additional information	Based on available data, the classification criteria are not met.
Respiratory or skin sensitisation	Not classified.
Additional information	Based on available data, the classification criteria are not met.
Germ cell mutagenicity	Not classified.
Additional information	Based on available data, the classification criteria are not met.
Carcinogenicity	Not classified.
Additional information	Based on available data, the classification criteria are not met.
Reproductive toxicity	Not classified.
Additional information	Based on available data, the classification criteria are not met.
Specific target organ toxicity (single exposure)	Not classified.
Additional information	Based on available data, the classification criteria are not met.
Aspiration hazard	Not classified.
Additional information	Based on available data, the classification criteria are not met.
Potential adverse human health effects and symptoms:	Not expected to present a significant hazard under anticipated conditions of normal use.

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11.2 Information on other hazards

This product does not contain any known or suspected endocrine disrupting properties for human health. To the best of our knowledge, data on the chemical, physical, and toxicological properties are not available. Hazardous properties cannot be excluded but are unlikely when the product is handled appropriately.

SECTION 12: Ecological information

12.1 Toxicity

Lyo-Ready Genotyping Direct qPCR Urine, 4x	
Ecology - Water	Not Classified

Environmental hazards must not be labelled with P phrases until 125 mL or 125 g (EU 1272/2008 Annex I - 1.5.2).

12.2 Persistence and degradability

Lyo-Ready Genotyping Direct qPCR Urine, 4x	
Biodegradation	No data available

12.3 Bioaccumulative potential

Lyo-Ready Genotyping Direct qPCR Urine, 4x	
Bioconcentration factor (BCF REACH)	No additional information available
Log Pow	Not applicable

12.4 Mobility in soil

Lyo-Ready Genotyping Direct qPCR Urine, 4x	
Ecology - Soil	No data available.

12.5 Results of PBT and vPvB assessment

Lyo-Ready Genotyping Direct qPCR Urine, 4x	
This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII	
This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII	

12.6 Endocrine disrupting properties

Assess endocrine disrupting properties for the environment:

Substance identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605: NONE

12.7 Other adverse effects

Lyo-Ready Genotyping Direct qPCR Urine, 4x	
No additional information available.	

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Waste disposal recommendations:	Product Offer surplus and non-recyclable solutions to a licensed disposal company.
	Contaminated packaging Dispose of as unused product.

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SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

14.1 UN number

UN-No. (ADR)	Not regulated
UN-No. (IMDG)	Not regulated
UN-No. (IATA)	Not regulated
UN-No. (ADN)	Not regulated
UN-No. (RID)	Not regulated

14.2 UN proper shipping name

Proper Shipping Name	Not regulated
Proper Shipping Name (IMDG)	Not regulated
Proper Shipping Name (IATA)	Not regulated
Proper Shipping Name (ADN)	Not regulated
Proper Shipping Name (RID)	Not regulated

14.3 Transport hazard class(es)

Transport hazard class(es) (ADR)	Not regulated
Transport hazard class(es) (IMDG)	Not regulated
Transport hazard class(es) (IATA)	Not regulated
Transport hazard class(es) (ADN)	Not regulated
Transport hazard class(es) (RID)	Not regulated

14.4 Packing group

Packing group	Not regulated
Packing group (IMDG)	Not regulated
Packing group (IATA)	Not regulated
Packing group (ADN)	Not regulated
Packing group (RID)	Not regulated

14.5 Environmental hazards

Dangerous for the environment	No
Marine pollutant	No
Other information	No supplementary information available

14.6 Special precautions for user

Overland transport	Not regulated
Transport by sea	Not regulated
Air transport	Not regulated
Inland waterway transport	Not regulated
Rail transport	Not regulated

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code

Not applicable

SECTION 15: Regulatory information

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

Contains no REACH substances with Annex XVII restrictions
 Contains no substance on the REACH candidate list $\geq 0,1\%$ / SCL
 Contains no REACH Annex XIV substances

15.2 Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other Information

16.1 Full text of H, EUH and P statements

None	N/A
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16.2 Training Advice

Regular safety training

16.3 Abbreviations and acronyms

ADR	Accord européen relatif au transport international des marchandises Dangereuses par Route
ATE	Acute Toxicity Estimate
CAS	Chemical Abstracts Service number
CLP	Classification, Labeling and Packaging
DNEL	Derived No effect Limit
EC	European Community
EC50	Effective Concentration 50%
EN	European Norm
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IBC	Intermediate Bulk Container
IMDG	International Maritime Dangerous Goods Code
IMO	International Maritime Organisation
LC50	Lethal Concentration 50%
LD50	Lethal Dose 50%
MAC	Maximal Allowed Concentration
O/W	Oil-in-Water (chemistry)
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent, bioaccumulative and toxic
PMcc	Pensky-Martens Closed Cup test
PNEC	Predicted no effect concentration
REACH	Registration, Evaluation and Authorisation of CHemicals
RID	Règlement concernant le transport international ferroviaire de marchandises
STEL	Short Term Exposure Limit
TWA	Time Weighted Average
UNXXXX	Number assigned by the United Nations Committee of Experts on the Transport of Dangerous Goods
vPvB	Very persistent and very bioaccumulative

16.4 Recommended Restriction on Use

Only for professional user working under controlled conditions.
 Consider employee restrictions for young people (e.g. 94/33/EC)
 Consider employee restrictions for pregnant women and nursing women (e.g. 92/85/EEC)

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16.5 Further Information

Bioline Reagents Ltd, part of Meridian Bioscience, provides the information contained herein in good faith being up-to-date of own realizations at revision time. This document is intended only as a guide to the appropriate precautionary handling of the material by a properly trained person using this product. Individuals receiving the information must exercise their independent judgement in determining its appropriateness for a particular purpose.

Bioline Reagents Ltd, part of Meridian Bioscience, makes NO REPRESENTATIONS or WARRANTIES, either expressed or implied, including without limitation any warranties of merchantability, fitness for a particular purpose with respect to the information set forth herein or the product to which the information refers.

Accordingly, **Bioline Reagents Ltd**, Meridian Bioscience or other subsidiaries, will not be responsible for damages resulting from use of or reliance upon this information. See terms and conditions at the end of our price lists for additional information.

16.6 Sources of Key Data

UK – Control of Substances Hazardous to Health Regulations 2002 (as amended). Health and Safety at Work etc. Act 1974 (as amended). Guidance Workplace Exposure Limits EH40.

EU – 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, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. Regulation 453/2010/EU REACH - REQUIREMENTS FOR THE COMPILATION OF SAFETY DATA SHEETS Regulation 487/2013/EU, 4th adaptation of CLP regulation to technical and scientific progress. Legislation Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (as amended). Commission Regulation (EU) No 2020/878.

German act governing protection from hazardous substances (Chemicals Act / Chemikaliengesetz- ChemG), revised on August 2013 German order governing protection from hazardous substances (Ordinance on Hazardous Substances /

Gefahrstoffverordnung - GefStoffV), revised on November 2010, according to Directive 98/24/EC

TRGS 900, German engineering rules governing limits in air at work, updated February 2015 SUVA .CH, Limits in air at work 2009, revised on 01.2009. KÜHN, BIRETT Merkblätter Gefährliche Arbeitsstoffe (Data Sheets of Hazardous Substances)., updated October 2011

Republic of China – 职业病防治法

USA – Occupational Safety and Health Administration (OSHA) Occupational Exposure Limits - Table Z-1 Limits for Air Contaminants. The American Conference of Governmental Industrial Hygienists (ACGIH).

Australia - Work Health and Safety (WHS) Act and the WHS Regulations.

Canada – Hazardous Products Regulations SOR/2015-17