Ingenetix Products

Version: 03 Revision date: 2024-03-14

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

1.1 Product identifier

Products: valid for all Ingenetix products of the product groups ViroReal®, BactoReal®, MycoReal®, ParoReal®, FetoGnost®, PanReal, ControlReal as well as Internal Positive Control

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

Only to be used for professional in-vitro diagnostic, veterinary diagnostic, or research use. The use case of each product is specified in the instructions-for-use (IFU) and on the product label.

1.3 Details of the supplier of the safety data sheet

Manufacturer: Ingenetix GmbH
Address: Haidingergasse 1, 1030 Vienna, Austria
Phone: +43(0)1 36 1980 1
E-mail: office@ingenetix.com

1.4 Emergency phone number

+43 1 406 43 43 (Gesundheit Österreich GmbH, 24 h)

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

This product does not meet the criteria for classification according to Regulation No. 1272/2008/EC.

2.2 Label elements

Labelling according to REGULATION (EC) No. 1272/2008

Hazard pictograms:	Not necessary
Signal word:	Not necessary
Hazard statements:	Not necessary
Precautionary statements:	Not necessary

Hazardous components which must be listed on the label
None

2.3 Other hazards

Not known

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

This product is a mixture.

3.2 Mixtures

Assay Mix contains primers, probes and HPLC grade water.
Reaction Mix contains enzymes, proteins, dNTPs, ROX dye and buffer.
Positive control contains plasmids or oligos and buffer.

The concentration of the chemicals used in preparation of the components is very negligible in the final buffer concentration. The product has no classification under CLP and does not fall under SVHC as per REACH Regulation (EC) No1907/2006.

SECTION 4: FIRST-AID MEASURES

4.1 Description of first aid measures

General advice: Rinse thoroughly with plenty of water. Consult a physician. Show this safety data sheet to the doctor in attendance.

If inhaled: Move to fresh air. Consult a physician.
In case of skin contact: If on skin, rinse well with water. If on clothes, remove clothes. Consult a physician.
In case of eye contact: Rinse thoroughly with plenty of water. Consult a physician.
If swallowed: Clean mouth with water and drink plenty of water. Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

None known.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Unsuitable extinguishing media: High volume water jet

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting: Do not allow run-off from firefighting to enter drains or water courses.
Hazardous combustion products: None known.

5.3 Advice for firefighters

Special protective equipment for firefighters: Wear self-contained breathing apparatus for firefighting if necessary.
Further information: Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel: Bring people to safety.
For emergency responders: Use personal protective equipment. Refer to protective measures listed in sections 7 and 8.

6.2 Environmental precautions

Given the way of dispensation, there is no possibility of accidental spillage in sufficient quantity to be dangerous. Avoid release to the environment.

6.3 Methods and material for containment and cleaning up

Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust). Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

Treat recovered material as described in the section "Disposal considerations".

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Advice on safe handling: Good Laboratory Practices (disposal gloves). Not to eat, drink and smoke in work areas. Avoid contact and contamination with skin, eyes and clothes. Use disposal gloves. Specimens should be handled as potentially infectious materials.
Advice on protection against fire and explosion: Normal measures for preventive fire protection
Hygiene measures: When using do not eat or drink. When using do not smoke. Wash hands before breaks and at the end of workday.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers: Keep container tightly closed in a dry and well-ventilated place. Containers which are opened must be carefully resealed and kept upright to prevent leakage. Electrical installations / working materials must comply with the technological safety standards.
Further information on storage conditions: See label, package insert or internal guidelines.

Further information on storage stability: No decomposition if stored and applied as directed.

7.3 Specific end use(s)

Specific use(s): No further relevant information available.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Occupational Exposure Limits: No data available.

8.2 Exposure controls

Engineering measures: No data available.

Personal protective equipment
Eye protection: Eye wash bottle with pure water. Safety goggles.
Hand protection: Protective gloves according to EN 374.
Skin and body protection: Wear appropriate protective safety wear and clothing, such as a lab coat and a mask.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical state	liquid
Colour Reaction Mix and Positive Control:	opaque to light yellow
Colour Assay Mix:	blue to violet (depending on the dye of the probe)
Odour:	no data available
Odour Threshold:	no data available
Melting point/range:	no data available
Boiling point/range:	no data available
Flammability	the product is not flammable, does not sustain combustion
Upper explosion/flammability limit:	no data available
Lower explosion/flammability limit	no data available
Flash point:	no data available
Auto-ignition temperature:	no data available
Decomposition temperature:	no data available
pH:	about 6.0 – 8.0
Viscosity dynamic/kinematic:	no data available
Water solubility:	no data available
Solubility in other solvents:	no data available
Partition coefficient: n-octanol/water:	no data available
Vapour pressure:	no data available
Relative density:	no data available
Relative vapour density:	no data available

9.2 Other information

Oxidizing properties:	the substance or mixture is not classified as oxidizing
Flammability (liquids):	does not sustain combustion
Self-ignition:	no data available
Evaporation rate:	no data available
Miscibility with water:	completely miscible

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No dangerous reaction known under conditions of normal use.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

None known.

10.4 Conditions to avoid

None known.

10.5 Incompatible materials

None known.

10.6 Hazardous decomposition products

No known hazardous decomposition products.

SECTION 11: TOXICOLOGICAL INFORMATION

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

Acute toxicity: Not classified based on available information.
Skin corrosion/irritation: Not classified based on available information.
Serious eye damage/eye irritation: Not classified based on available information.
Respiratory or skin sensitisation: Not classified based on available information.
Germ cell mutagenicity: Not classified based on available information.
Carcinogenicity: Not classified based on available information.
Reproductive toxicity: Not classified based on available information.
STOT – single/repeated exposure: Not classified based on available information.
Repeated dose toxicity: Not classified based on available information.
Aspiration toxicity: Not classified based on available information.
Information on other hazards: None

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

None known. Discard in a proper biohazard container after testing. Do not allow to reach ground water, water bodies or sewage systems.

12.2 Persistence and degradability

None known.

12.3 Bioaccumulative potential

None known.

12.4 Mobility in soil

None known.

12.5 Results of PBT and vPvB assessment

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.

12.6 Endocrine disrupting properties

None known.

12.7 Other adverse effects

An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product: After testing, the product must be disposed of compliance with the respective local, state or national regulations.

Contaminated packaging: Empty remaining contents. Dispose of as unused product. Empty containers should be taken to an approved waste handling site for recycling or disposal. Do not re-use empty containers.

SECTION 14: TRANSPORT INFORMATION

14.1 UN number or ID number: Not regulated as a dangerous good.

14.2 UN proper shipping name: Not regulated as a dangerous good.

14.3 Transport hazard class(es): Not regulated as a dangerous good.

14.4 Packing group: Not regulated as a dangerous good.

14.5 Environmental hazards: Not regulated as a dangerous good.

14.6 Special precautions for user: Not dangerous goods in the meaning of ADR/RID, ADN, IMDG-Code, ICAO/IATA-DGR.

14.7 Maritime transport in bulk according to IMO instruments: Not applicable

SECTION 15: REGULATORY INFORMATION

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

This product does not require special labelling, in accordance with the appropriate regulations.

15.2 Chemical safety assessment

Chemical safety assessments for all substances in this product are either complete or not applicable.

SECTION 16: OTHER INFORMATION

Consult instructions for use prior to product use. Professional use only for in vitro diagnosis.

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

SECTION 17: CHANGE HISTORY

Rev. No.	Date	Reason for change	Created by
03	2024-03-14	Addition of non-IVD-products to 1.1 *Product identifier* and 1.2 *Relevant identified uses of the substance or mixture and uses advised against*	Matthias Rauch
02	2023-08-18	Addition of product group “FetoGnost®” to 1.1 *Product identifier*	Matthias Rauch
01	2023-04-18	Initial document	Simone Sturm-E.