

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830 Revision Date 05.02.2025

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

1.1 Product identifier

VICSIPET Product name

> TROPHECTODERM BIOPSY **BLASTOMERE BIOPSY**

Product form Substance

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

Industrial/Professional use spec For professional use only.

Use of the substance/mixture For the collection of trophectoderm cells respectively of blastomeres

for subsequent preimplantation genetic diagnosis.

Uses advised against No additional information available.

1.3 Details of the supplier of the safety data sheet

Manufacturer VITROMED GmbH

Göschwitzer Str. 22 07745 Jena Germany

support@vitromed.com

1.4 Emergency telephone number

+49 3641 5 39 19 76 **Emergency number**

SECTION 2 – HAZARDS IDENTIFICATION

2.1 Emergency telephone number

Classification (EC) No 1272/2008 Not classified.

Adverse physicochemical, human health and environmental effect

No additional information available.

2.2 Label elements

Labelling according to Regulation

(EC) No. 1272/2008

No labelling applicable.

2.3 Other hazards

No additional information available

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substance

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008
Borosilicate glass	1	100	Not classified

Full text of H-phrases: see section 16

3.2 Mixture

Not applicable.

Comments V-ICSIPET does not contain any raw materials of direct animal-origin or

materials that have been produced using animal-origin components. Components have not been in contact with material of animal origin

during processing and therefore pose no TSE risk.

SECTION 4 – FIRST AID MEASURES

4.1 Description of first aid measures

Never give anything by mouth to an unconscious person. If you feel First-aid measures general

unwell, seek medical advice (show the label where possible).

First-aid measures after inhalation Allow affected person to breathe fresh air. Allow the victim to rest. First-aid measures after skin contact No data available.

Rinse immediately with plenty of water. Obtain medical attention if pain, First-aid measures after eye contact

blinking or redness persist.

First-aid measures after ingestion Rinse mouth. Do NOT induce vomiting. Obtain emergency medical

attention.

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4.2 Most important symptoms and effects, both acute and delayed

Symptoms/injuries Not expected to present a significant hazard under anticipated

conditions of normal use.

4.3 Indication of any immediate medical attention and special treatment needed

No additional information available.

SECTION 5 – FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media Pipettes are non-combustible. Unsuitable extinguishing media Do not use a heavy water stream.

5.2 Special hazards arising from the substance or mixture

No additional information available.

5.2 Advice for firefighters

Firefighting instructions Use extinguishing media that is appropriate for the classification of the

surrounding fire.

Protection during firefighting Possibility of flying glass fragment if hot glass comes in contact with water

or carbon dioxide extinguishing media.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment, and emergency procedures

Emergency procedures Evacuate unnecessary personnel.

Protective equipment Equip cleanup crew with proper protection.

Ventilate area. **Emergency procedures**

6.2 Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up Store away from other materials.

6.3 Reference to other sections

See Heading 8. Exposure controls and personal protection.

SECTION 7 – HANDLING AND STORAGE

7.1 Precautions for safe handling

No data available Precautions for safe handling

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions Store in dry environment. Avoid excessive humidity. Keep only in the

original container away from direct (sun)light. Do not use after expiry

date. Cannot be resterilized after opening.

Incompatible products Strong bases. Strong acids.

Incompatible materials Sources of ignition. Direct (sun)light.

Storage temperature No data available

7.3 Specific end uses(s)

See instructions for use delivered with the product.

SECTION 8 – EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

No additional information available.

8.2 Exposure controls

Appropriate engineering controls If glass dust or particulates are above the national permissible exposure

limits use a national approved respirator for dust and fibers. Industrial safety glasses that meet national standards. Recommend gloves for protection from cutting of hands and wrists sharp edges. The national standards/limits are to be checked with the appropriate authorities.

Personal protective equipment Wear fire/flame resistant/retardant clothing.

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Skin protection Complete suit protecting against chemicals, flame retardant antistatic

protective clothing. The type of protection must be selected according to the concentration and volume of the dangerous substance at the

specific workplace.

Hand protection Wear protective 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. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to meet specifications of regulation EU 2016/425

and the standard EN374.

Eye/Face protection Face shield and safety glasses. Use equipment for eye protection tested

and approved under appropriate government standards such as NIOSH

(US) or EN 166 (EU).

Respiratory protection Wear appropriate mask. Where risk assessment shows air-purifying

respirators are appropriate use a full-face respirator with multi-purpose combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government

standards such as NIOSH (US) or CEN (EU).

Other information Do not eat, drink or smoke during use. Do not pipette liquid using a

mouth pipette.

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical state

Appearance Various forms and shapes.

Colour Color clear. Odour No odor.

Odour threshold No data available No data available Relative evaporation rate (butylacetate=1) No data available **Melting point** No data available Freezing point No data available **Boiling** point No data available Flash point No data available **Auto-ignition temperature** No data available **Decomposition temperature** No data available

Flammability (solid, gas) Non flammable No data available Vapour pressure Relative vapour density at 20°C No data available Relative density No data available Solubility Not soluble in water Log Pow No data available Viscosity, kinematic No data available Viscosity, dynamic No data available **Explosive properties** No data available Oxidising properties No data available **Explosive limits** No data available

9.2 Other information

No additional information available. Other properties

SECTION 10 – STABILITY AND REACTIVITY

10.1 Reactivity

No additional information available.

10.2 Chemical stability

Stable for 5 years after date of manufacture.

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10.3 Possibility of hazardous reactions

Not established.

10.4 Conditions to avoid

Direct (sun)light.

10.5 Incompatible materials

Strong acids. Strong bases.

10.6 Hazardous decomposition products

No additional information available.

SECTION 11 – TOXICOLOGIAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity (oral, dermal, inhalation) Not classified.

Extensive data from Mouse Embryo Assays have demonstrated that the

medium is not toxic.

Skin corrosion/irritationNot classified.

Additional informationBased 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 sensitizationNot classified.

Additional information Based on available data, the classification criteria are not met.

Germ cell mutagenicity Not classified.

Additional informationBased on available data, the classification criteria are not met.

Carcinogenicity Not classified

Additional informationBased on available data, the classification criteria are not met.

Reproductive toxicityNot classified.

Additional informationBased on available data, the classification criteria are not met.

STOT-single exposure Not classified

Additional informationBased on available data, the classification criteria are not met.

STOT-repeated exposure Not classified

Additional information

Based on available data, the classification criteria are not met.

Aspiration hazardNot classified

Additional information

Based on available data, the classification criteria are not met.

Potential adverse human health

Based on available data, the classification criteria are not met.

effects and symptoms

SECTION 12 - ECOLOGICAL INFORMATION

12.1 Toxicology

Hazardous to the aquatic

environment, short-term (acute)

Not classified.

Hazardous to the aquatic environment, long-term (chronic)

Not classified.

12.2 Persistence and degradability

Not established.

12.3 Bioaccumulative potential

Not established.

12.4 Mobility in soil

No additional information available.

12.5 Results of PBT and vPvB assessment

No additional information available.

12.6 Other adverse effects

Avoid release to the environment.

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SECTION 13 – DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product / packaging disposal recommendations **Ecology - waste materials**

Dispose in a safe manner in accordance with local/national regulations.

Avoid release to the environment.

SECTION 14 – TRANSPORT INFORMATION

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

14.1 UN number

Not regulated for transport.

14.2 UN proper shipping name

Proper Shipping Name (ADR) Not applicable. Proper Shipping Name (IMDG) Not applicable. Proper Shipping Name (IATA) Not applicable. Proper Shipping Name (ADN) Not applicable. Proper Shipping Name (RID) Not applicable.

14.3 Transport hazard class(es)

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

14.4 Packing group

Packing group (ADR) Not applicable. Packing group (IMDG) Not applicable. Packing group (IATA) Not applicable. Packing group (ADN) Not applicable. Packing group (RID) Not applicable.

14.5 Environmental hazards

Dangerous for the environment No Marine pollutant No

Other information No supplementary information available.

14.6 Special precautions for user

No data available. Overland transport No data available. Transport by sea Air transport No data available. No data available. Inland waterway transport Rail transport No data available.

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

Not applicable.

SECTION 15 – REGULATORY INFORMATION

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

EU-Regulations Contains no REACH substances with Annex XVII restrictions.

Contains no substance on the REACH candidate list.

Contains no REACH Annex XIV substances.

Contains no substance subject to REGULATION (EU) No 649/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 concerning

the export and import of hazardous chemicals.

Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants.

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National regulations

Germany

Water hazard class (WGK) No WGK, not hazardous to water (Classification according to AwSV,

Annex 1)

Hazardous Incident Ordinance

(12. BlmSchV)

Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

This product is not hazardous under the criteria of the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200. To the best of our knowledge, this product contains no levels of listed substances, which the state of California has found to cause cancer, birth defects or other reproductive effects.

15.2 Chemical safety assessment

No chemical safety assessment has been carried out.

SECTION 16 – OTHER INFORMATION

Data sources 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.

Other information None

SDS EU (REACH Annex II)

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