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

1.1 Product identifier

Product name

vCENTERWELL
vCULTUREDISH
vCRYOVIAL
vICSIDISH
v4WELLDISH
vROUNDTUBE
vCONICALTUBE
vSAMPLE CONTAINER
vSEROLOGICAL PIPET
vTRANSFER PIPET
vTIP

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 examination of specimens, e.g. sperm, oocytes and tissue, derived from the human body.

Uses advised against No additional information available

1.3 Details of the supplier of the safety data sheet

Manufacturer

VITROMED GmbH
Göschwitzer Straße 22
07745 Jena
Germany
support@vitromed.com
+49 3641 5 39 19 76

1.4 Emergency telephone number

Emergency number +49 3641 5 39 19 76; Available Monday to Friday, 8:00-17:00, German and English.

SECTION 2 – HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification-(EC) No 1272/2008 This substance does not meet the criteria for classification in accordance with Regulation No 1272/2008/EC

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

According to the results of its assessment, this substance is not a PBT or a vPvB.

Does not contain an endocrine disruptor (ED) at a concentration of ≥ 0,1%.

SECTION 3 – COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008
Polyethylene	(CAS No) 9002-88-4	/	Not classified
Polypropylene	(CAS No) 9003-07-0	/	Not classified
Polystyrene	(CAS No) 9003-53-6	/	Not classified
Silicone	(CAS No) 90337-93-2	/	Not classified

3.2 Mixtures

Not applicable.

Comments	IVF Labware products do 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

First-aid measures general	Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
First-aid measures after inhalation	Not an expected route of exposure under intended use.
First-aid measures after skin contact	No data available.
First-aid measures after eye contact	Not an expected route of exposure. If particles or fragments enter the eye, rinse cautiously with water. Seek medical attention if irritation persists.
First-aid measures after ingestion	Rinse mouth. Do not induce vomiting. Seek medical advice if the product or fragments are accidentally swallowed.

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 is available.

SECTION 5 – FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media	Foam. Dry powder. Carbon dioxide. Water spray. Sand.
Unsuitable extinguishing media	Do not use a heavy water stream.

5.2 Special hazards arising from the substance or mixture

Combustion may produce carbon monoxide, carbon dioxide, smoke, and irritating fumes.

5.3 Advice for firefighters

Firefighting instructions	Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering environment.
Protection during firefighting	Do not enter fire area without proper protective equipment, including respiratory protection.

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.
Emergency procedures	Ventilate area.

6.2 Environmental precautions

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

6.3 Methods and material for containment and cleaning up

Methods for cleaning up	Collect the products or fragments mechanically and place them in an appropriate waste container. If contaminated with biological material, dispose of them in accordance with the laboratory's procedures for contaminated waste. Store away from other materials.

6.4 Reference to other sections

See Sections 8 and 13.

SECTION 7 – HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling	Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid damage to the product and packaging. Provide good ventilation in process area.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions	Do not use after expiry date. The content cannot be re-sterilized after opening. Keep only in the original container away from direct (sun)light. Keep container closed when not in use. Store in dry environment. Avoid excessive humidity. Do not expose products to unintended sources of irradiation.
Incompatible products	Sources of ignition.
Incompatible materials	Strong bases. Strong acids. Strong oxidizing agents, Chlorine, permanganates, for example potassium permanganate
Storage temperature	Room temperature.

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 occupational exposure limits are applicable to the product in its supplied form.

8.2 Exposure controls

Appropriate engineering controls	No special engineering controls are required when the product is handled and used as intended in IVF and ART procedures. Follow applicable laboratory hygiene procedures and measures intended to prevent contamination of the product and biological material.
Personal protective equipment	Laboratory clothing and other protective equipment should be worn in accordance with the laboratory's procedures, the applicable risk assessment, and the biological materials, media, reagents, or samples being handled.
Skin protection	Wear suitable laboratory clothing in accordance with the laboratory's procedures. Additional skin protection should be selected based on the biological or chemical materials used during the procedure. No specific skin protection is required solely for handling the product in its finished form as intended.
Hand protection	Wear suitable disposable laboratory gloves in accordance with the laboratory's procedures. Inspect gloves before use and apply an appropriate glove-removal technique to prevent contamination. Dispose of used or contaminated gloves in accordance with applicable procedures and regulations. Wash and dry hands after removing gloves. Where protection against chemicals or biological materials is required, gloves shall be selected based on the applicable risk assessment and relevant requirements, such as Regulation (EU) 2016/425 and EN ISO 374.
Eye/Face protection	Eye protection should be used where required by the laboratory risk assessment, particularly when handling biological samples, culture media, cryogenic materials, or liquids presenting a splash risk. Where required, use eye protection compliant with EN 166 or another applicable standard.
Respiratory protection	No respiratory protection is required solely for handling the product as intended. Where respiratory protection is required because of other materials or processes used in the laboratory, it shall be selected based on the applicable workplace risk assessment.
Other information	Do not eat, drink or smoke during use. Do not pipette liquid using a mouth pipette. Wash hands after removing gloves and upon completion of the procedure.

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical state	Solid. Finished laboratory article; product-specific shape and dimensions.
Appearance	Transparent or product specific
Colour	Clear, colourless or product specific
Odour	Odourless
Odour threshold	No data available
pH	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)	Combustible; not classified as a flammable solid based on available information
Vapour pressure	No data available
Relative vapour density at 20°C	No data available
Density and/or relative density	No data available
Solubility	Insoluble in water under normal conditions
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

Other properties No additional information available

SECTION 10 – STABILITY AND REACTIVITY

10.1 Reactivity

No additional information available

10.2 Chemical stability

Stable after transport under normal ambient and anticipated storage and handling conditions.

10.3 Possibility of hazardous reactions

Contact with strong oxidizing agents should be avoided.

10.4 Conditions to avoid

Direct sunlight, extreme temperatures, uncontrolled irradiation, open flames, and use outside the conditions specified in the instructions for use.

10.5 Incompatible materials

Strong acids. Strong bases.

10.6 Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products are not expected. Thermal decomposition or combustion may produce carbon monoxide, carbon dioxide, smoke, and irritating fumes.

SECTION 11 – TOXICOLOGIAL INFORMATION

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

Acute toxicity (oral, dermal, inhalation)	>2000 mg/kg Rat (ECHA) (oral, dermal)
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 sensitization	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.
STOT-single exposure	Not classified.
Additional information	Based 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 hazard	Not classified.
Additional information	Based on available data, the classification criteria are not met.
Potential adverse human health effects and symptoms	Based on available data, the classification criteria are not met.

11.2 Information on other hazards

Endocrine disrupting properties	Does not contain an endocrine disruptor (ED) at a concentration of ≥ 0,1%.
Additional information	Based on available data, the classification criteria are not met.
Other information	Not classified.
Additional information	Based on available data, the classification criteria are not met.

SECTION 12 – ECOLOGICAL INFORMATION

12.1 Toxicity

Hazardous to the aquatic environment, short-term (acute)	Shall not be classified as hazardous to the aquatic environment.
Hazardous to the aquatic environment, long-term (chronic)	Shall not be classified as hazardous to the aquatic environment.

12.2 Persistence and degradability

Data are not available.

12.3 Bioaccumulative potential

Data are not available.

12.4 Mobility in soil

Data are not available.

12.5 Results of PBT and vPvB assessment

Not applicable to the finished article. Based on available raw-material information, no constituent material has been identified as containing PBT or vPvB substances at relevant concentrations.

12.6 Endocrine disrupting properties

Based on available information, the constituent materials have not been identified as containing substances with endocrine-disrupting properties at concentrations of 0.1% or greater.

12.7 Other adverse effects

Avoid release to the environment.

SECTION 13 – DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product / packaging disposal recommendations	Dispose in a safe manner in accordance with local/national regulations. Used products that have contacted human specimens, biological materials, media, or reagents shall be disposed of according to the laboratory's procedures and applicable requirements for contaminated or potentially infectious waste.
Ecology - waste materials	Avoid release to the environment.

SECTION 14 – TRANSPORT INFORMATION

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

14.1 UN number or ID number

Not subject to transport regulations

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

Overland transport	No data available
Transport by sea	No data available
Air transport	No data available
Inland waterways transport	No data available
Rail transport	No data available

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

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

National regulations

Germany

Water hazard class (WGK)	No WGK, not hazardous to water (Classification according to AwSV, Annex 1).
Hazardous Incident Ordinance (12. BImSchV)	Is not subject of the Hazardous Incident Ordinance (12. BImSchV).

15.2 Chemical safety assessment

No chemical safety assessment has been carried out.

SECTION 16 – OTHER INFORMATION

Revision history

Template V_FB_919 MSDS template_E_03 used for Version 04 of this document.

Section 3, text "Full text of H-phrases: see section 16" deleted.

Removal of substances: 9003-55-8 and 8012-95-1.

Sections 4-13 updated.

Abbreviations and acronyms

Acronym	Definition
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	Agreement concerning the International Carriage of Dangerous Goods by Road

ART	Assisted reproductive technology
CAS	Chemical Abstracts Service
EN	European Standard
EU	European Union
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods Code
IVF	In vitro fertilisation
PBT	Persistent, bioaccumulative and toxic
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STOT	Specific target organ toxicity
TSE	Transmissible spongiform encephalopathy
vPvB	Very persistent and very bioaccumulative
WGK	Water hazard class, *Wassergefährdungsklasse*

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

This safety information has been prepared for the finished article in its supplied form and under its intended conditions of use. Safety data sheets for the constituent raw materials were reviewed as supporting information.

The raw-material safety data sheets describe materials in forms such as granules, pellets, powders, laboratory chemicals, or processing materials. Precautions concerning dust formation, bulk handling, chemical processing, elevated temperatures, respiratory protection, chemical-protective clothing, and firefighting are therefore not directly applicable to the normal handling and intended use of the finished article.

Additional precautions may be required if the article is mechanically processed, heated above its intended-use conditions, burned, or otherwise used outside its intended purpose.

SDS EU (REACH Annex II)

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