

Safety Data Sheet

Technoview Organan CAL



SDS No 337.01
Date of issue 28-Jun-2022
Date of revision n.a.

Temp.: TF0366.01
Art. 01 to D00068

ACCORDING TO EC-REGULATIONS 1907/2006 (REACH), 1272/2008 (CLP) & 2020/878

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

1.1 Product identifier

Product Name/Reference No.	Technoview Organan CAL 5 x 1mL	REF 5090110-RUO
CAS No.	Not applicable.	
EC No.	Not applicable.	
REACH Registration No.	Not known.	

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

Identified Use(s)	For research use only
Uses Advised Against	Not known.

1.3 Details of the supplier of the safety data sheet

Manufacturer	
Company Identification	Technoclone Herstellung von Diagnostika und Arzneimitteln GmbH
Address of Manufacturer	Brunner Strasse 67 1230 Vienna Austria
Postal code	1230
Telephone:	+43 1 86373-0
Fax	+43 1 86373-44
E-mail	products@technoclone.com
Office hours	8:00 – 16:00

1.4 Emergency telephone number

Emergency Phone No.	+43 1 86373-0
Contact	products@technoclone.com
National response center	
Address	NHS Direct
Emergency Phone No.	+44 111

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Regulation (EC) No. 1272/2008 (CLP)	Not classified as dangerous for supply/use
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2.2 Label elements

	According to Regulation (EC) No. 1272/2008 (CLP)
Product Name	Technoview Organan CAL
Hazard Pictogram(s)	None.
Signal Word(s)	None.
Hazard Statement(s)	None.
Precautionary Statement(s)	None.

2.3 Other hazards

None known.

2.4 Additional Information

The product contains human plasma that tested negative for HIV antibody, Hepatitis B Surface Antigen and Anti-HCV. This product, as with all specimens of human origin, should be regarded as potentially infectious and handled with proper care for handling of biological material.

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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Not applicable.

3.2 Mixtures

HAZARDOUS INGREDIENT(S)	CAS No.	EC No. / REACH Registration No.	%W/W	Hazard Statement(s)	Hazard Pictogram(s)
Blood plasma, citrated, lyophilized	83732-46-1	280-593-2/ n.a.	98.00	Not classified.	None
Glycine	56-40-6	200-272-2/ n.a.	1.00	Not classified.	None
4-(2-hydroxyethyl)piperazin-1-ylethanesulphonic acid	7365-45-9	230-907-9/n.a.	1.00	Not classified	None

Contains no non-classified vPvB substances or substances with a Union workplace exposure limit.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Inhalation If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.
Skin Contact Wash skin with water.
Eye Contact Flush eyes with water for at least 15 minutes.
Ingestion Wash out mouth with water.

4.2 Most important symptoms and effects, both acute and delayed

None anticipated. Treat symptomatically.

4.3 Indication of any immediate medical attention and special treatment needed

Unlikely to be required but if necessary treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable Extinguishing media As appropriate for surrounding fire.
Unsuitable extinguishing media None.

5.2 Special hazards arising from the substance or mixture

None anticipated. Heating may cause decomposition.

5.3 Advice for firefighters

As appropriate for surrounding fire.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Provide adequate ventilation. Wear suitable gloves if prolonged skin contact is likely.

6.2 Environmental precautions

Do not release large quantities into the surface water or into drains.

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6.3 Methods and material for containment and cleaning up

Sweep spilled substances into containers if appropriate moisten first to prevent dusting.

6.4 Reference to other sections

See Also Section 8, 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Not known.

7.2 Conditions for safe storage, including any incompatibilities

Storage temperature	Ambient.
Storage life	Stable under normal conditions.
Incompatible materials	None known.

7.3 Specific end use(s)

Not known.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

8.1.1 Occupational Exposure Limits No Occupational Exposure Limit assigned.

8.2 Exposure controls

8.2.1. Appropriate engineering controls	Ensure adequate ventilation.
8.2.2. Personal protection equipment	
Eye Protection	Wear eye protection with side protection (EN166).
Skin protection	Not normally required.
Respiratory protection	Normally no personal respiratory protection is necessary.
Thermal hazards	None known.
8.2.3. Environmental Exposure Controls	Do not release large quantities into the surface water or into drains.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical state	Solid, freeze-dried powder
Colour	White to yellowish
Odour	odourless
Melting point/freezing point	Not known.
Boiling point or initial boiling point and boiling range	Not applicable.
Flammability	Not known.
Lower and upper explosion limit	Not known.
Flash Point	Not applicable.
Auto-ignition temperature	Not known.
Decomposition Temperature	Not known.
pH	Not known.
Kinematic Viscosity	Not known.
Solubility	Solubility (Water) : readily miscible. Solubility (Other) : Not known

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Partition coefficient n-octanol/water (log value) Not known.
Vapour pressure Not known.
Density and/or relative density Not known.
Relative vapour density Not known.
Particle characteristics Not known.

9.2 Other information

None.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

None anticipated.

10.2 Chemical Stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

No hazardous reactions known if used for its intended purpose.

10.4 Conditions to avoid

None anticipated.

10.5 Incompatible materials

Not known.

10.6 Hazardous decomposition products

No hazardous decomposition products known.

SECTION 11: TOXICOLOGICAL INFORMATION

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

Acute toxicity - Ingestion	Low acute toxicity
Acute toxicity - Skin Contact	Low acute toxicity
Acute toxicity - Inhalation	Low acute toxicity
Skin corrosion/irritation	Non-irritant
Serious eye damage/irritation	Non-irritant
Skin sensitization data	Not classified
Respiratory sensitization data	Not classified
Germ cell mutagenicity	There is no evidence of mutagenic potential.
Carcinogenicity	No evidence of carcinogenicity.
Reproductive toxicity	Not classified
Lactation	Not classified
STOT - single exposure	Not classified
STOT - repeated exposure	Not classified
Aspiration hazard	Not classified

11.2 Information on other hazards

Not known.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Toxicity - Aquatic invertebrates	Low toxicity to invertebrates.
Toxicity - Fish	Low toxicity to fish.
Toxicity - Algae	Low toxicity to algae.

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Toxicity - Sediment Compartment Not classified.
Toxicity - Terrestrial Compartment Not classified.

12.2 Persistence and degradability

Not known.

12.3 Bioaccumulative potential

Not known.

12.4 Mobility in soil

Not known.

12.5 Results of PBT and vPvB assessment

Not known.

12.6 Endocrine disrupting properties

None known.

12.7 Other adverse effects

Not known.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Dispose at suitable refuse site.

13.2 Additional Information

No special precautions are required for this product.

SECTION 14: TRANSPORT INFORMATION

Not classified as hazardous for transport.

14.1 UN number or ID number

Not applicable

14.2 UN proper shipping name

Not applicable

14.3 Transport hazard class(es)

Not applicable

14.4 Packing group

Not applicable

14.5 Environmental hazards

Not classified as a Marine Pollutant.

14.6 Special precautions for user

Not known

14.7 Maritime transport in bulk according to IMO instruments

Not known

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SECTION 15: REGULATORY INFORMATION

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

European Regulations - Authorisations and/or Restrictions On Use

Candidate List of Substances of Very High Concern for Authorisation Not listed

REACH: ANNEX XIV list of substances subject to authorisation Not listed

REACH: Annex XVII Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles Not listed

Community Rolling Action Plan (CoRAP) Not listed

Regulation (EC) N° 850/2004 of the European Parliament and of the Council on persistent organic pollutants Not listed

Regulation (EC) N° 1005/2009 on substances that deplete the ozone layer Not listed

Regulation (EU) N° 649/2012 of the European Parliament and of the Council concerning the export and import of hazardous chemicals Not listed

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National regulations

Other Not known.

15.2 Chemical Safety Assessment

A REACH chemical safety assessment has not been carried out.

SECTION 16: OTHER INFORMATION

The following sections contain revisions or new statements:

LEGEND

Hazard Pictogram(s)	None.
Hazard classification	None
Hazard Statement(s)	None.
Precautionary Statement(s)	None.
Acronyms	ATE : Acute Toxicity Estimate CAS : Chemical Abstracts Service CLP : Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures DNEL : Derived No Effect Level EC : European Community EINECS : European Inventory of Existing Commercial Chemical Substances LTEL : Long term exposure limit PBT : Persistent, Bioaccumulative and Toxic PNEC : Predicted No Effect Concentration REACH : Registration, Evaluation, Authorisation and Restriction of Chemicals STEL : Short term exposure limit STOT : Specific Target Organ Toxicity vPvB : very Persistent and very Bioaccumulative

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Key literature references and sources for data used to compile the SDS

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