



SAFETY DATA SHEET

In compliance with Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances, Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices and mixtures, REACH Regulation (EC) No 1907/2006 and Commission Regulation (EU) 2021/979 amendment, and U.S. OSHA Hazard Communication 29CFR1910.1200

Section 1: Product Identification

1.1 Product Name/Product Identifier:		Cell-Free DNA BCT® RUO	Synonyms:		N/A
International Chemical Identification:		N/A			
CAS Number:	N/A, Mixture	EC Number:	N/A	Index Number:	N/A
1.2 Product Use:	Stabilization of cell-free plasma DNA				
Restrictions:	Refer to Instructions for Use (IFU) for additional precautions and limitations.				

1.3 Manufacturer:	Streck
Address:	7002 S. 109 St, La Vista, NE, 68128
Prepared by:	Jeff Hopkins, Industrial Safety Coordinator
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1.4 Emergency:	Business hours (8:00 AM to 5:00 PM CST): 1-402-333-1982
	24hr (Chem.-Tel): 1-800-255-3924

Section 2: Hazards Identification

Product is < 0.22ml of self-contained solution and hazards are neutralized upon sample collection. Refer to IFU for proper handling.

2.1 Classification:					
Regulation (EC) No 1272/2008 [CLP]	Cat.	H code	Symbol	Signal Word	Classification Procedures
Skin Sensitization:	1B	H317	Exclamation 	Warning	Bridging principles: Dilution

Hazard pictograms: Exclamation Mark (GHS07)

Signal Word: Warning

2.2 Label Elements: Container labeling is not required on medical devices per 29CFR1910.1200(b)(5)(iii) & Regulation (EU) 2017/746.

Hazard Statements:	
H317	May cause an allergic skin reaction

Precautionary Statements:	
P260	Do not breathe dust/fume/gas/mist/vapors/spray
P302 + P352 +	IF ON SKIN: Wash with plenty of soap and water.
P304 + P340 +	IF INHALED: Remove person to fresh air and keep comfortable for breathing.

2.3 Other hazards: Contains no PBT or vPvB substances according to REACH No 1907/2006. This mixture does not contain substances with endocrine disrupting properties in accordance with the criteria in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

Section 3: Composition

3.1 Substances: This product is a mixture.

3.2 Mixtures: Cell-Free DNA BCT® RUO contains an anticoagulant and a cell preservative in a liquid medium.

Name	CAS No	EC No	Content	Classification
Tripotassium EDTA	65501-24-8	676-659-9	≤ 10%	Acute Tox. 4; STOT RE 2; H332, H373
Germall 115 (IDU)	39236-46-9	254-372-6	≤ 50%	Skin Sens. 1B, H317

Section 4: First Aid Measures

4.1 Description of First Aid Measures

No data available

4.2 Most important symptoms and effects, both acute and delayed:

The most important known symptoms and effects are described in the labeling (see section 2.2) and/or in section 11.

4.3 Indication of immediate medical attention and special treatment needed:

No data available

Section 5: Fire Fighting Measures

5.1 Suitable Extinguishing media	Use water spray, dry sand, alcohol-resistant foam, dry chemical or carbon dioxide. No unsuitable extinguishing media known.
5.2 Special hazards arising from the chemical	Carbon oxides, nitrogen oxides (NOx), Potassium oxides.
5.3 Special protective equipment and precautions for firefighters.	Wear self-contained breathing apparatus for firefighting if necessary.

Section 6: Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

PPE needed for clean up: Use personal protective equipment. Ensure adequate ventilation.

6.2 Environmental Precautions

N/A

6.3 Methods and materials for containment and cleaning up

Spill clean-up procedure: Take up spill or leak with absorbent material and place in a suitable waste container. Spilled product and cleanup materials should be treated as non-hazardous waste.

Follow-up guidelines: Flush spill area with water.

6.4 Reference to other sections

N/A

Section 7: Handling and Storage

Refer to Instructions for Use (IFU) and labeling for handling and storage.

7.1 Handling	Avoid contact with skin and eyes. Provide appropriate exhaust ventilation. Normal measures of preventive fire protection.		
7.2 Storage	Keep container tightly closed in a dry and well-ventilated place.		
Temp	As indicated on product labeling.	Avoid	Strong oxidizing agents. Avoid contact with skin and eyes. Avoid formation of dust and aerosols.
Warnings	Ensure adequate ventilation.		

Section 8: Exposure Control and Personal Protection

8.1 Control Parameters:	
Occupational exposure limits:	Not applicable
Biological limit values:	Not applicable
Exposure limits at intended use	Not applicable
DNEL	Not applicable
PNEC	Not applicable
Risk management measures according to used control banding approach	Not applicable

8.2 Exposure Controls		
Engineering controls	Handle in accordance with good industrial hygiene and safety practices.	
Personal Protective equipment	Skin Protection	<p>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; dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices; wash and dry hands.</p> <p>Full Contact: Material: Nitrile Rubber Minimum layer thickness: 0.4 mm Break through time: 480 min</p>
	Eye Protection	Wear safety glasses with side shields or face shield tested and approved under appropriate government standards such as EN 166(EU).
	Body Protection	Standard Laboratory clothing protecting against chemical exposure.
	Respiratory Protection	No special protective equipment required.

Section 9: Physical and Chemical Properties

Appearance			
Physical State	Liquid	Color	Colorless
Odor	No Odor	Odor Threshold	No Data Available

	Value	Concentration	Method	Temperature	Pressure	Remark
pH	5.60	N/A	N/A	N/A	N/A	
Melting/ Freezing point	N/A	N/A	N/A	N/A	N/A	No Data Available
Boiling point/ Boiling range	N/A	N/A	N/A	N/A	N/A	No Data Available
Flash Point	>93 °C	N/A	N/A	N/A	N/A	
Evaporation rate	N/A	N/A	N/A	N/A	N/A	No Data Available
Flammability	N/A	N/A	N/A	N/A	N/A	No Data Available
Upper/lower flammability	N/A	N/A	N/A	N/A	N/A	No Data Available
Upper explosive limits	N/A	N/A	N/A	N/A	N/A	No Data Available
Lower explosive limits	N/A	N/A	N/A	N/A	N/A	No Data Available
Vapor pressure	23.8 mmHg @ 25°C	N/A	N/A	N/A	N/A	
Vapor density	N/A	N/A	N/A	N/A	N/A	No Data Available
Relative density	N/A	N/A	N/A	N/A	N/A	No Data Available
Solubility(ies)	N/A	N/A	N/A	N/A	N/A	Water Solubility
Partition coefficient: n-octano/ water	N/A	N/A	N/A	N/A	N/A	No Data Available
Auto-ignition temperature	N/A	N/A	N/A	N/A	N/A	No Data Available
Decomposition Temperature	N/A	N/A	N/A	N/A	N/A	No Data Available
Viscosity	N/A	N/A	N/A	N/A	N/A	No Data Available
Viscosity, dynamic	N/A	N/A	N/A	N/A	N/A	No Data Available
Viscosity, cinematic	N/A	N/A	N/A	N/A	N/A	No Data Available
Explosive properties	N/A	N/A	N/A	N/A	N/A	No Data Available
Oxidising properties	N/A	N/A	N/A	N/A	N/A	No Data Available

Other information:

All hazards are based on bridging techniques for the mixture and no testing has been conducted on the completed mixture.

Physical Hazards			
Explosives	Not Applicable	Flammable gases	Not Applicable
Flammable aerosols	Not Applicable	Oxidizing gases	Not Applicable
Gases under pressure	Not Applicable	Flammable Liquids	Not Applicable
Flammable Solids	Not Applicable	Self-reactive substances and mixtures	Not Applicable
Pyrophoric Liquids	Not Applicable	Pyrophoric Solids	Not Applicable
Self-heating substances and mixtures	Not Applicable	Substances or mixtures which, in contact with water emit flammable gases	Not Applicable
Oxidizing Liquids	Not Applicable	Oxidizing solids	Not Applicable
Organic Peroxides	Not Applicable	Metal Corrosion	Not Applicable

Section 10: Stability and Reactivity

10.1 Reactivity: No data available

10.2 Chemical Stability: Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions: No data available

10.4 Conditions to avoid: Avoid contact with skin and eyes.

10.5 Incompatible materials: Strong oxidizing agents, bases and acids.

10.6 Hazardous decomposition products: Hazardous decomposition products formed under fire conditions – Carbon oxides, Nitrogen oxides (NOx), Ammonia, Hydrogen fluoride, Sodium oxides and Potassium oxides

Section 11: Toxicological Properties

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

Toxicological effects:	No Data Available
Route(s) of exposure:	Eyes, skin, respiratory and digestive system
Symptoms:	Causes skin, eye respiratory and digestive tract irritation.
Delayed effects:	No Data Available
Immediate effects:	Can irritate with minimal exposure
Chronic effects:	Short exposure: No Data Available
	Long exposure: No Data Available
Exposure limits	No Data Available
Carcinogenicity	Components of product listed as a carcinogen to humans under the International Agency for Research on Cancer (IARC) and known human carcinogen under the National Toxicity Program (NTP).
Measures of Toxicity	No Data Available

Acute Toxicity						
Practical experience/ human evidence:			N/A*			
Animal Data						
Mixture	Effect dose/ - concentration	Value	Species	Method	Symptoms/ delayed effects	Remark
Dermal	N/A	N/A	N/A	N/A	N/A	*
Inhalation	N/A	N/A	N/A	N/A	N/A	*
Oral	N/A	N/A	N/A	N/A	N/A	*
*Bridging Principles (Dilution) utilized to determine hazards. Highest hazards selected based on substance. No testing or calculations available for mixture.						
Other information:			N/A			
Assessment/ Classification						
Dermal	N/A	Inhalation	N/A		Oral	N/A

Skin corrosion/ Irritation					
Practical experience/ human evidence:			N/A		
Acid -/ Alkali reserve (buffer capacity for mixtures and extreme pH values)					
Acidic reserve (g NaOH/100 g product):		N/A	Alkaline reserve [g H ₂ SO ₄ /100 g product]:		N/A
Animal Data					
	Species	Method	Exposure Time	Result/Evaluation	Remark
Mixture	N/A	N/A	N/A	N/A	*
*Bridging Principles (Dilution) utilized to determine hazards. Highest hazards selected based on substance. No testing or calculations available for mixture.					
In-vitro skin test			N/A		
Other information			N/A		
Assessment/ Classification			N/A		

Eye damage/ irritation				
Practical experience/ human evidence:			N/A	
Animal Data				
	Species	Method	Result/Evaluation	Remark
Mixture	N/A	N/A	N/A	*
*Bridging Principles (Dilution) utilized to determine hazards. Highest hazards selected based on substance. No testing or calculations available for mixture.				
In-vitro eye test			N/A	
Other information			N/A	
Assessment/ Classification			N/A	

Skin Sensitization						
Practical experience/ human evidence:			N/A			
Animal Data						
	Effect dose/ - concentration	Value	Species	Method	Result/ Evaluation	Remark
Mixture	N/A	N/A	N/A	N/A	N/A	*
*Bridging Principles (Dilution) utilized to determine hazards. Highest hazards selected based on substance. No testing or calculations available for mixture.						
Other information			N/A			
Assessment/ Classification			N/A			

CMR effects (Carcinogenicity, mutagenicity and toxicity for reproduction)

Germ Cell Mutagenicity							
In vitro mutagenicity/ genotoxicity							
	Cell type/ Organism	Genetic Endpoint	Method	Result/ evaluation	Remark		
Mixture	N/A	N/A	N/A	N/A	*		
*Bridging Principles (Dilution) utilized to determine hazards. Highest hazards selected based on substance. No testing or calculations available for mixture.							
In vivo mutagenicity/ genotoxicity							
	Effect dose/ - concentration	Value	Cell type/ Organism	Genetic Endpoint	Method	Result/ evaluation	Remark
Mixture	N/A	N/A	N/A	N/A	N/A	N/A	*
*Bridging Principles (Dilution) utilized to determine hazards. Highest hazards selected based on substance. No testing or calculations available for mixture.							
Other Information				N/A			
Assessment/ Classification				N/A			

Carcinogenicity								
Practical experience/ human evidence:			N/A					
Animal Data								
	Effect dose/ - concentration	Value	Exposure Route	Exposure Time	Species	Method	Result/ evaluation	Remark
Mixture	N/A	N/A	N/A	N/A	N/A	N/A	N/A	*
*Bridging Principles (Dilution) utilized to determine hazards. Highest hazards selected based on substance. No testing or calculations available for mixture.								
Other information		N/A						
Assessment/ Classification		N/A						

Specific target organ toxicity: Single Exposure								
Practical experience/ human evidence:								
Animal Data								
	Effect dose/ - concentration	Value	Exposure duration	Species	Method	Specific Effects	Organs affected	Remark
Dermal	N/A	N/A	N/A	N/A	N/A	N/A	N/A	*
Inhalation	N/A	N/A	N/A	N/A	N/A	N/A	N/A	*
Oral	N/A	N/A	N/A	N/A	N/A	N/A	N/A	*
*Bridging Principles (Dilution) utilized to determine hazards. Highest hazards selected based on substance. No testing or calculations available for mixture.								
Other information			N/A					
Assessment/ Classification								
Dermal	N/A	Oral	N/A		Respiratory		N/A	

Mixtures:

Bridging Principles (Dilution) utilized to determine hazards. Highest hazards selected based on substance. No testing or calculations available for mixture.

11.2 Information on other hazards: N/A

Section 12: Ecological Information

12.1 Toxicity: No Data Available

12.2 Persistence and degradability: No Data Available

12.3 Bioaccumulative potential: No Data Available

12.4 Mobility in soil: No Data Available

12.5 Results of PBT and vPvB assessment: No Data Available

12.6 Endocrine disrupting properties: This mixture does not contain substances with endocrine disrupting properties in accordance with the criteria in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

12.7 Other adverse effects: None

Section 13: Disposal Considerations

13.1 Waste Treatment Methods: To the best of our knowledge, this material does not require special disposal considerations. Adhere to local, state and federal regulations with regard to disposal of this product. Dispose of unused BCTs as non-hazardous waste. Dispose of used BCTs in same manner as patient sample.

Section 14: Transport Information

14.1 UN number or ID number: N/A

14.2 UN proper shipping name: N/A

14.3 Transport hazard class(es): N/A

14.4 Packing group: N/A

14.5 Environmental hazards: N/A

14.6 Special precautions for user: N/A

14.7 Maritime transport in bulk according to IMO instruments: N/A

14.8 Other: This material is not regulated by either IATA or DOT.

Section 15: Regulatory Information

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

U.S. Federal Regulations SARA 311/312 Hazards Toxic Substances Control Act (TSCA)	No SARA Hazards No substances are subject to a Significant New Use Rule No substances are subject to TSCA 12(b) export notification requirements
U.S. State Regulations California Proposition 65	This product does not contain any components on the California Proposition 65 list
International Regulations DSL Status	Some components of this product are on the Canadian DSL or NDSL lists.
European Union (EU) Regulation (EC) No 1272/2008 Regulation (EU) 2017/746 Regulation (EC) No 1907/2006	Classification, labelling and packaging of substances In Vitro Diagnostic Medical Devices and mixtures Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
German Ordinance on Facilities Handling Substances that are Hazardous to Water (AwSV)	Water Hazard Class (WGK2)

15.2 Chemical safety assessment: For this mixture, a chemical safety assessment has not been carried out.

Section 16: Other

This product is intended for use as supplied.

To the best of our knowledge, the information contained herein is accurate. However, Streck assumes no liability whatsoever for completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist

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