

## 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

<b>1.1 Product Name/Product Identifier:</b>	Cell-Free DNA BCT® CE	<b>Synonyms:</b>	N/A
<b>International Chemical Identification:</b>	N/A		
<b>CAS Number:</b>	N/A, Mixture	<b>EC Number:</b>	N/A
<b>Index Number:</b>	N/A		
<b>Hazard components for labelling:</b>	Substances used with the mixture are proprietary and withheld as a trade secret.		
<b>1.2 Product Use:</b>	Stabilization of cell-free plasma DNA		
<b>Restrictions:</b>	Refer to Instructions for Use (IFU) for additional precautions and limitations.		
<b>Reasons:</b>	Product is classified as an In Vitro Diagnostic device.		

<b>1.3 Manufacturer:</b>	Streck
<b>Address:</b>	7002 S. 109 St, La Vista, NE, 68128
<b>Prepared by:</b>	Jeff Hopkins, Industrial Safety Coordinator
<b>E-mail:</b>	jhopkins@streck.com
<b>1.4 Emergency:</b>	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
Acute Toxicity:	Dermal	3	H311	Skull & Crossbones 	Danger	Bridging principles: Dilution
	Inhalation	3	H331			
	Oral	3	H301			
Carcinogenic		1A	H350	Health Hazard 	Danger	
Germ Cell Mutagenicity		2	H341	Health Hazard 	Warning	
Skin Corrosion		1B	H314	Corrosion 	Danger	

Skin Sensitization		1	H317	Exclamation 	Warning
Serious eye damage/ Irritation		1	H318	Corrosion 	Danger
Specific target organ toxicity: Single Exposure:	Dermal	1	H370	Health Hazard 	Danger
	Oral	1	H370		
	Respiratory	1	H370		
Aquatic Toxicity	Acute	3	H402	Environmental Hazard 	Warning

**Hazard pictograms:** Corrosion (GHS05), Exclamation Mark (GHS07), Health Hazard (GHS08), Skull & Crossbones (GHS06), Environment (GHS09)

**Signal Word:** Danger

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

Hazard Statements:	
H370	Causes damage to organs via dermal, oral, and respiratory routes.
H350	May cause cancer
H341	Suspected of causing genetic defects
H317	May cause an allergic skin reaction
H314	Causes severe skin burns and eye damage
H318	Causes serious eye irritation
H311	Toxic in contact with skin
H331	Toxic if inhaled
H301	Toxic if swallowed

Precautionary Statements:	
P201 + P202 + P281	Do not handle until all safety precautions have been read and understood. Use personal protective equipment as required.
P260 + P270 + P271	Do not breathe dust/fume/gas/mist/vapors/spray. Use only outdoors or in a well-ventilated area. Do not eat, drink or smoke when using this product.
P233 + P403 + P405 + P501	Keep container tightly closed. Store in a well-ventilated place. Store locked up. Dispose of contents/container of unused BCTs as non-hazardous waste. Dispose of used BCTs in the same manner as patient samples.
P264	Wash skin thoroughly after handling.
P303 + P361 + P352 + P353 + P363 + P313 + P333 + P312	<b>IF ON SKIN (or hair):</b> Remove/Take off immediately all contaminated clothing. Wash contaminated clothing before reuse. Rinse skin with water/shower. Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention. Call a POISON CENTER or doctor/physician if you feel unwell.
P305 + P310 + P351 + P338	<b>IF IN EYES:</b> Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/physician.
P304 + P340 + P307 + P311	<b>IF INHALED:</b> Remove victim to fresh air and keep at rest in a position comfortable for breathing. If exposed: Call a POISON CENTER or doctor/physician

P301 + P310 + P330 + P331 + P307 + P311	<b>IF SWALLOWED:</b> Immediately call a POISON CENTER or doctor/physician. Rinse mouth. Do NOT induce vomiting. If exposed: Call a POISON CENTER or doctor/physician
P308 + P313	If exposed or concerned: Get medical advice/ attention.

**2.3 Other hazards: N/A**

**Section 3: Composition**

**3.1/3.2 Description of the mixture:** Cell-Free DNA BCT® CE contains an anticoagulant and a cell preservative in a liquid medium.

Specific chemical formula is being withheld as a trade secret pursuant to 29 CFR Section 1910.1200(i)(1) and Regulation (EC) 1271/2008.

Refer to Section 2 for hazard information.

**Section 4: First Aid Measures**

**4.1 Description of First Aid Measures**

**General Information:** Consult a physician. Show this safety data sheet to the doctor in attendance.

**List specific first aid measures for:**

- Skin Contact** - Remove any contaminated clothing. Rinse the contacted area with water; then wash with soap and water. Wash clothing before reuse. Consult a physician.
- Eye contact** - Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
- Ingestion** - Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.
- Inhalation** - If breathed in, move person into fresh air. If not breathing give artificial respiration. Consult a physician.

**Self-protection of the first aider:** Personal protection equipment (PPE).

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

Irritation of skin, eyes and/or respiratory system may occur.

**4.3 Indication of immediate medical attention and special treatment needed:**

No data available

**Section 5: Fire Fighting Measures**

<b>5.1 Suitable Extinguishing media</b>	Use water spray, dry sand, alcohol-resistant foam, dry chemical or carbon dioxide.
<b>Unsuitable Extinguishing media</b>	No unsuitable extinguishing media known.
<b>5.2 Special hazards arising from the chemical</b>	Carbon oxides, Nitrogen oxides (NOx), Potassium oxides
<b>5.3 Special protective equipment and precautions for fire-fighters.</b>	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.

<b>7.1 Handling</b>	Avoid contact with skin, eyes and clothing. Provide appropriate exhaust ventilation. Normal measures of preventive fire protection.		
<b>7.2 Storage</b>	Keep container tightly closed in a dry and well-ventilated place		
<b>Temp</b>	As indicated on product labeling.	<b>Avoid</b>	Strong oxidizing agents. Bases. Acids. Avoid contact with skin and eyes. Avoid formation of dust and aerosols.
<b>Warnings</b>	Ensure adequate ventilation.		
<b>7.3 Specific end use(s)</b>	N/A		

**Section 8: Exposure Control and Personal Protection**

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

<b>8.2 Exposure Controls</b>		
<b>Engineering controls</b>	Handle in accordance with good industrial hygiene and safety practices.	
<b>Personal Protective equipment</b>	<b>Skin Protection</b>	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.  Full Contact: Material: Nitrile Rubber Minimum layer thickness: 0.4 mm Break through time: 480 min
	<b>Eye Protection</b>	Wear safety glasses with side shields or face shield tested and approved under appropriate government standards such as EN 166(EU)
	<b>Body Protection</b>	Standard Laboratory clothing protecting against chemical exposure.

	<b>Respiratory Protection</b>	No special protective equipment required.
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## **Section 9: Physical and Chemical Properties**

### **9.1 Information on basic physical and chemical properties**

<b>Appearance</b>			
<b>Physical State</b>	Liquid	<b>Color</b>	Colorless
<b>Odor</b>	No Odor	<b>Odor Threshold</b>	No Data Available

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

## 9.2 Other information:

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

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

<b>Toxicological effects:</b>	No Data Available
<b>Route(s) of exposure:</b>	Eyes, skin, respiratory and digestive system
<b>Symptoms:</b>	Causes skin, eye respiratory and digestive tract irritation.
<b>Delayed effects:</b>	No Data Available
<b>Immediate effects:</b>	Can irritate with minimal exposure
<b>Chronic effects:</b>	Short exposure: No Data Available
	Long exposure: No Data Available
<b>Exposure limits</b>	No Data Available
<b>Carcinogenicity</b>	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).
<b>Measures of Toxicity</b>	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	Category 3		Inhalation	Category 3		Oral	Category 3

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 <sub>2</sub> SO <sub>4</sub> /100 g product]:	N/A		
Animal Data					
Mixture	Species	Method	Exposure Time	Result/Evaluation	Remark
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.					
In-vitro skin test		N/A			
Other information		N/A			
Assessment/ Classification		Category 1B			

Eye damage/ irritation				
Practical experience/ human evidence:		N/A		
Animal Data				
Mixture	Species	Method	Result/Evaluation	Remark
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 eye test		N/A		
Other information		N/A		
Assessment/ Classification		Category 1		

Skin Sensitization						
Practical experience/ human evidence:				N/A		
Animal Data						
Mixture	Effect dose/ - concentration	Value	Species	Method	Result/ Evaluation	Remark
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				Category 1		

## 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				Category 2			

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				Category 1A				

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	Category 1	Oral	Category 1	Respiratory	Category 1			

### 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 Other adverse effects:** No Data Available

## **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. Treat product as a patient sample. 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:**

<b>U.S. Federal Regulations</b> OSHA Hazards SARA 311/312 Hazards Toxic Substances Control Act (TSCA)	Irritant Acute Health Hazard, Chronic Health Hazard
<b>U.S. State Regulations</b> California Proposition 65	Reproductive Toxicity to both males and females
<b>International Regulations</b> DSL Status	Some components of this product are on the Canadian DSL or NDSL lists.
<b>European Union (EU)</b> Regulation (EC) No 1272/2008 Regulation (EU) 2017/746	Classification, labelling and packaging of substances In Vitro Diagnostic Medical Devices and mixtures
<b>German Ordinance on Facilities Handling Substances that are Hazardous to Water (AwSV)</b>	Water Hazard Class (WGK3)

**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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