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, Directive 98/79/EC on In Vitro Diagnostic Medical Devices and mixtures, and U.S. OSHA Hazard Communication 29CFR1910.1200.

Section 1: Product Identification

Product Name/Product Identifier:		RNA Complete BCT®	**Synonyms:**	N/A		
International Chemical Identification:		N/A				
CAS Number:	N/A, Mixture	**EC Number:**	N/A	**Index Number:**	N/A	
Hazard components for labelling:		Substances used with the mixture are proprietary and withheld as a trade secret.				
Product Use:	Stabilization of blood specimens					
Restrictions:	Refer to Instructions for Use (IFU) for additional precautions and limitations.					
Reasons:	Product is classified as an In Vitro Diagnostic device.					

Manufacturer:	Streck
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Section 2: Hazards Identification

Product is self-contained. Hazards are neutralized upon sample collection. Refer to IFU for proper handling.

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			

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

Signal Word: Danger

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/vapours/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 same manner as patient sample.
P264	Wash skin thoroughly after handling.
P303 + P361 + P352 + P353 + P363 + P313 + P333 + P312	**IF ON SKIN (or hair):** 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	**IF IN EYES**: 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	**IF INHALED:** 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	**IF SWALLOWED:** 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.

Other hazards: N/A

Section 3: Composition

Description of the mixture: This product 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 Art. 15 of 1999/45/EC.

Refer to Section 2 for hazard information.

Section 4: First Aid Measures

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

List specific first aid measures for:

1. **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.
2. **Eye contact -** Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
3. **Ingestion -** Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.
4. **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).

Most important symptoms and effects, both acute and delayed:
Irritation of skin, eyes and/or respiratory system may occur.

Indication of immediate medical attention and special treatment needed:
No data available

Section 5: Fire Fighting Measures

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

Section 6: Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

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

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.

Section 7: Handling and Storage

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

Section 8: Exposure Control and Personal Protection

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

Exposure Controls		
Engineering controls	Handle in accordance with good industrial hygiene and safety practices.	
Personal Protective equipment	**Skin Protection**	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
	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

Information on basic physical and chemical properties

Appearance			
Physical State	Liquid	**Color**	Slight yellow color
Odor	No Odor	**Odor Threshold**	No Data Available

	Value	Concentration	Method	Temperature	Pressure	Remark
pH	5.15	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-octanol/ 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
Oxidizing properties	N/A	N/A	N/A	N/A	N/A	No Data Available

Section 10: Stability and Reactivity

1. **Reactivity:** No data available
2. **Chemical Stability:** Stable under recommended storage conditions.
3. **Possibility of hazardous reactions:** No data available
4. **Conditions to avoid:** Avoid contact with skin and eyes.
5. **Incompatible materials:** Strong oxidizing agents
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

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	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 H2SO4/100 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			Category 1B		

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			Category 1	

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			Category 1			

CMR effects (Carcinogenity, 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.

Other information: N/A

Section 12: Ecological Information

No Data Available

Section 13: Disposal Considerations

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

This material is not regulated by either IATA or DOT.

Section 15: Regulatory Information

U.S. Federal Regulations	
OSHA Hazards	Irritant
SARA 311/312 Hazards	Acute Health Hazard, Chronic Health Hazard
Toxic Substances Control Act (TSCA)	
U.S. State Regulations	
California Proposition 65	Reproductive Toxicity to both males and females
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	Classification, labelling and packaging of substances
Directive 98/79/EC	In Vitro Diagnostic Medical Devices and mixtures

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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