

Safety Data Sheet

Section 1. Product and Company Identification

Product Name Mutation Quantification Control Plasma with 50ng/250ng spike in DNA
Catalog # Z2010003/Z2010004
Manufacturer Biochain Institute, Inc.
39600 Eureka Drive
Newark, CA 94560
USA
510.783.8588 or 1.888.762.2568
Email: info@biochain.com

Emergency Phone # Contact your local hazardous material control center.
Call 911 in case of medical emergency.

Relevant identified uses of the substance or mixture and uses advised against
Molecular PCR assays

Note The pharmacological, toxicological, and ecological properties of this product/mixture have not been fully characterized. This data sheet will be updated as more data become available.

Section 2. Hazards Identification

Classification of the substance or mixture
Globally Harmonized System [GHS] Mixture not yet fully tested.

Label elements	None required
GHS hazard pictogram	None required
GHS signal word	Warning
GHS hazard statements	None required
GHS precautionary statements	None required

Other hazards The potential health hazards associated with exposure/handling of this mixture are unknown; no data specific for the mixture were identified. The following data describe the hazards of individual ingredients, where applicable.

This product/mixture contains human plasma and should be treated/handled as a potential biohazard. All such human source material has been derived from donors tested individually and shown by FDA approved methods to be free from antibodies to Human Immune Deficiency Virus and Hepatitis B and C. As no test method can offer complete assurance that these or other infectious agents are not present, this product should be handled using standard biosafety precautions. Products may contain active pathogens. Please refer to package insert for additional information, and handle product as potentially biohazardous

Note This mixture is classified as hazardous according to Regulation EC No 1272/2008 (EU CLP) and Hazard Communication Standard No. 1910.1200 (US OSHA). The pharmacological, toxicological and ecological properties of this mixture have not been fully characterized.

Section 3. Composition and Information on Ingredients

All components of the kit are considered non-hazardous.

<u>Ingredient</u>	<u>CAS #</u>	<u>EINECS/ELIN CS#</u>	<u>Amount</u>	<u>GHS Classification</u>
Human Source Material	N/A	N/A	>99%	Not classified
Tromethamine (Tris {hydroxymethyl} aminomethane)	77-86-1	201-064-4	≤0.2%	SI2: H315; EI2: H319; STOT-SE3: H335
Ethylenediaminetetraacetic acid tetrasodium salt (EDTA)	60-00-4	200-449-4	≤0.04%	ATO4: H302; SC2: H315; ED2A: H319; STOT-SE3: H335
Sodium Azide	26628-22-8	247-852-1	0 – 0.05%	ATO2: H300; AA1: H400 , CA1: H410; EUH032

Note The ingredient(s) listed above are considered hazardous. The remaining components are non-hazardous and/or present at amounts below reportable limits. Product contains trace levels of unencapsulated DNA. Although unencapsulated DNA is not known to be dangerous, it is recommended that the product be handled as potentially biohazardous. See Section 16 for full text of CLP/GHS classifications. The GHS classification is based on Regulation (EC) 1272/2008 and Hazard Communication Standard No. 1910.1200.

Section 4. First Aid Measures

Skin: Wash exposed skin with mild soap and water. Get medical attention if irritation develops or persists.

Eyes: Immediately flush with plenty of water for at least 15 minutes, occasionally lifting the upper and lower eyelids. Seek medical attention.

Inhalation: If breathing becomes difficult, move victim to fresh air. If irritation persists, get medical attention.

Ingestion: Do not induce vomiting. If affected person is conscious, give plenty of water to drink. Seek medical attention.

Section 5. Fire Fighting Measures

Flammability of the Product: Not flammable.

Flash Points: Not available

Section 6. Accidental Release Measures

Personal precautions, protective equipment and emergency procedures: If product is released or spilled, take proper precautions to minimize exposure by using appropriate personal protective equipment (see Section 8). Area should be adequately ventilated.

Environmental precautions: Do not empty into drains. Avoid release to the environment.

Methods and material for containment and cleaning up: DO NOT CAUSE MATERIAL TO BECOME AIRBORNE. For small spills, soak up material with absorbent, e.g., paper towels. For large spills, cordon off spill area and minimize the spreading of spilled material. Soak up material with absorbent. Collect spilled material, absorbent, and rinse water into suitable containers for proper disposal in accordance with applicable waste disposal regulations (see Section 13). Neutralize the residue with a dilute solution of acetic acid. Decontaminate the area twice with an appropriate solvent (see Section 9).

Section 7. Handling and Storage

Precautions for safe handling: Follow recommendations for handling pharmaceutical agents (i.e., use of engineering controls and/or other personal protective equipment if needed). Avoid contact with eyes, skin and other mucous membranes. Wash thoroughly after handling. Avoid breathing mist/spray. Keep away from heat. Keep away from sources of ignition. Ground all equipment containing material.

Conditions for safe storage including any incompatibilities: Store unopened bottles at -20°C or below. Open bottles are stable for up to 30 days at 2-8°C. Store in a well-ventilated area, away from incompatible materials. Keep container upright and tightly closed.

Specific end use(s): No information identified.

Section 8. Exposure Controls and Personal Protection

Control

Parameters/Occupational

Exposure Limit

Values

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Human Source Material	--	--	--
Tromethamine (Tris {hydroxymethyl } aminomethane)	--	--	--
Ethylenediaminetetraacetic acid tetrasodium salt (EDTA)	--	--	--
Sodium Azide	ACGIH, Australia, Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, Finland, France, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Malta, Netherlands, Poland, Romania, Slovakia, Slovenia,	OEL-STEL	0.3 mg/m ³

Spain, Sweden, U.S.- California OSHA, United Kingdom		
New Zealand,	Ceiling	0.29 mg/m ³
Portugal ACGIH, Australia, Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Malta, Netherlands, Poland, Romania, Slovakia, Slovenia, Spain, Sweden, U.S.- California OSHA, United Kingdom	OEL-TWA	0.1 mg/m ³
NIOSH, U.S.-California OSHA	Ceiling	0.3 mg/m ³
Germany	OEL-STEL	0.4 mg/m ³
Germany	OEL-TWA	0.2 mg/m ³

Exposure/Engineering controls

Selection and use of containment devices and personal protective equipment should be based on a risk assessment of exposure potential. Use local exhaust and/ or enclosure at aerosol/mist-generating points. Emphasis is to be placed on closed material transfer systems and process containment, with limited open handling.

Respiratory protection

Choice of respiratory protection should be appropriate to the task and the level of existing engineering controls. An approved and properly fitted air-purifying respirator with HEPA filters should provide ancillary protection based on the known or foreseeable limitations of existing engineering controls.

Section 9. Physical and Chemical Properties

N/A.

Section 10. Stability and Reactivity**Stability and Reactivity:** The product is stable**Section 11. Toxicological Information**

N/A

Section 12. Ecological Information

The product itself and its products of degradation are not toxic.

Section 13. Disposal Considerations

Please consult local, state and federal regulation on additional guidance on disposal.

Section 14. Transport Information

Contact BCI for all transport information.

Section 15. Regulatory Information

N/A.

Section 16. Other Information

The information contained in this SDS was obtained from sources we believe are reliable. However, the above information is provided without warranty, expressed or implied, regarding its correctness. The conditions or methods of handling, storage, use and disposal of the product are beyond our control and may be beyond our knowledge. 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.