

1. Identification of substance:

Product Name: Coag-o-trol I-II
Cat. No.: coag118
Application of the substance / the preparation: Laboratory reagent For In Vitro Diagnostic Use

Manufacturer/Supplier: **BGT BioGenTechnologies GmbH**
 Von-Langen-Weg 10 Tel.: 02551/4090
 D-48565 Steinfurt Fax: 02551/1298
 Germany www.biogentechnologies.de

Informing department: BGT customer service info@biogentechnologies.de
Emergency information: Health Toxicological Information Service (HTIS)
 during office hours Tel.: 02551/4090

2. Hazards identification

Hazard designation: N.A.
Information pertaining to particular dangers for man and environment:
 The product does not have to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.
Classification system: The classification is conform to current EC-directives

3. Composition/Data on components:

Chemical characterization:

Dangerous components according to EC-criteria: N.A.

C.A.S. number: 26628-22-8	Sodium-azide	R:28-32 S:28	<0,01%
N.A.	Lyophilized Rabbit Thromboplastin	N.A.	N.A.

4. First aid measures

General information: No special measures required.
Skin contact: Remove contaminated clothing immediately.
 Wash affected area twice with soap and water.
Eye contact: Promptly wash eyes with copious quantities of tepid water!
Ingestion: Keep the injured person warm and call for immediate medical attention!

5. Fire fighting measures

Suitable extinguishing agents: CO₂, extinguishing powder or foam or water.

Protective equipment: No special measures required.

Specific risks: Non determined

Additional recommendations: None

6. Accidental release measures:

Person-related safety precautions: Wear lab coat, protective gloves and safety goggles.

Measures for environmental protection: Do not allow to reach sewage system or water bodies.

Measures for cleaning/collecting: Absorb with liquid-binding material (diatomite, acid binders, universal binders).

Additional information: Human plasmas, used for the preparation have been tested for HIV Antibodies, HBs:Ag and HCV Antibodies, with registered methods. However, all human sourced material should be treated as potentially hazardous and the appropriate handling and disposal procedures must be adhered to, as no assay may totally exclude the presence of any infectious agent.

7. Handling and storage

Handling

Safe handling: No special measures required.

Protection against explosions and fires: No special measures required.

Storage

Storerooms and containers: No special requirements.

Storage in one common storage facility: Not required.

Further storage conditions: Protect from direct sunlight, store at 2-8 °C.

8. Exposure controls and personal protection

Components with limit values at the workplace: Not required.

Additional information: The lists that were valid during the compilation were used as basis.

General protective and hygienic measures: The usual precautionary measures should be adhered to general rules for handling chemicals.

Personal protective equipment:

Breathing equipment: Not necessary, if room is well-ventilated.

Hand protection: Protective gloves

Eye protection: Safety glasses recommended during refilling.

Skin protection: Lab coat.

Hygiene measures: Wash hands before and after use.

9. Physical and chemical properties

General Information

Form:	<i>Powder</i>
Colour:	<i>White</i>
Odour:	<i>Non-odorous</i>
Change in condition	
Melting point/Melting range:	<i>Not determined</i>
Boiling point/Boiling range:	<i>Not determined</i>
Flash point:	<i>Not applicable</i>
Self-inflammability:	<i>Product is not self-igniting</i>
Danger of explosion:	<i>Product is not explosive.</i>
Vapour pressure at 20°C:	<i>Not determined</i>
Density at 20°C	<i>Not determined</i>
Solubility in / Miscibility with Water:	<i>Not determined</i>
pH-value at 20°C:	<i>~7</i>
Viscosity:	<i>Not determined No data available</i>

Comment: Where 'No data available' appears by a property, that property has not been determined but should approximate water, which is the preparation's main component when reconstituted.

10. Stability and reactivity

Thermal decomposition / conditions to be avoided: *Fire or excessive heat may produce hazardous decomposition products. Stable liophilizate when stored at 2-8°C.*

Dangerous reactions *No dangerous reactions known.*

Dangerous products of decomposition: *No dangerous decomposition products known.*

11. Toxicological information

Acute toxicity: *Oral Rat LD₅₀ 1800 mg/kg
The toxicity estimate is for this dilute preparation, not for pure or concentrated substance.*

Primary irritant effect:

Skin: *Slightly irritant.*

Eye: *No irritant effect.*

Sensitization: *Prolonged and repeated skin exposure may cause sensitization.*

Additional toxicological information:

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

The material is not subject to classification according to EC lists in the last version.

12. Ecological information

Mobility:	<i>Not determined.</i>
Degradability:	<i>Not determined.</i>
Bio accumulative potential:	<i>Not determined.</i>
Ecotoxicology:	<i>Not determined.</i>
Other hazardous effects:	<i>None determined.</i>

13. Disposal considerations

Product:	
Recommendation:	<i>The product must be disposed of as a laboratory chemical according to local regulations.</i>
Contaminated packaging:	
Recommendation:	<i>Incineration. There are no uniform EC-regulations for the disposal of packaging as waste.</i>

14. Transport information

Land transport ADR/RID (cross-border)	
ADR/RID-GGVS/E Class:	-
Remarks:	<i>Not restricted</i>
Marine pollutant:	<i>No</i>
Air transport ICAO-TI and IATA-DGR:	
ICAO/IATA Class:	-
Remarks:	<i>Not restricted</i>

15. Regulatory information

Symbols:	<i>None</i>
R phrases:	<i>None</i>
S phrases:	<i>None</i>
Designation according to EC guidelines:	<i>Observe the normal safety regulations when handling chemicals. The product is not subject to identification regulations under EC Directives.</i>

16. Other information:

BGT provides the information in this data sheet in good faith, declaring it is up-to-date at time of revision. However this document is intended only as a guide for professional use, according to the intended purposes of the product. It does not represent a guarantee for the properties of the product described in terms of the legal warranty regulations.