

SUNBIO

SAFETY DATA SHEET

According to Regulation (EC) No. 1907/2006

Coagulation Factor Control Normal

Kit reagents: Coagulation Factor Control Normal

SDS No.: SDS-069

Version: A/0

Effecting Date: April 18, 2026

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier	Product Name:	Coagulation Factor Control Normal
1.2. Relevant identified uses of the substance or mixture and uses advised against	For <i>in vitro</i> diagnostic use.	
1.3 Details of the supplier of the safety data sheet	Manufacturer	European Authorized Representative
	Shanghai Sun Biotech Co.,Ltd.	Lotus NL B.V.
	No.3419 Jindu Road, Minhang District, 201108 Shanghai, P.R. China	Koningin Julianaplein 10,1e Verd, 2599AA, The Hague, Netherlands.
	Tel: +86-21-54425188 +86-21-64188590	Tel: +31644168999
	Fax : +86-21-54256603	
	shtysw@sunbiote.com	
1.4 Emergency telephone number	+86-21-54830665 / +86-13901753509	

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture	Product definition	Classification according to Regulation (EC) No. 1272/2008
	Mixture	Not classified
2.2 Label elements		
Signal word(s)	None	
Hazard statement(s)	None	
Precautionary statement(s)	None	
2.3 Other hazards	The product does not meet the criteria for PBT and vPvB.	
	Note: This product contains source materials of human origin. These materials were tested and found to be nonreactive for antibody to HIV-1 and HIV-2, antibody to hepatitis C (HCV) as well as for hepatitis B surface antigen (HbsAg). However, as it is not possible to offer complete assurance that infectious agents are not present, all materials of human origin should be handled as though they might contain potentially infectious agents.	

SECTION 3: Composition/information on ingredients

3.1 Substances	Not applicable
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3.2 Mixtures: Mixture

There are no ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment, and hence require reporting in this section.

SECTION 4: First aid measures

4.1 Description of first aid measures	Inhalation	If inhaled, move person to fresh air. If breathing is difficult, oxygen should be administered by qualified personnel. Get medical attention if adverse symptoms appear.
	Contact with skin	Immediately remove contaminated clothing. Wash thoroughly with soap and water. Get medical attention if adverse symptoms appear.
	Contact with eyes	Flush eyes with plenty of water for at least 15 minutes. If irritation or pain persists after fifteen minutes of eye irrigation, seek medical attention.
	Ingestion	If swallowed, get medical attention.
4.2 Most important symptoms and effects, both acute and delayed	No information available for the product.	
4.3 Indication of any immediate medical attention and special treatment needed	No data available.	

SECTION 5: Firefighting measures

5.1 Extinguishing media	Suitable extinguishing media	Foam. Dry powder. CO ₂ . Water spray.
	Unsuitable extinguishing media	Not known.
5.2 Special hazards arising from the substance or mixture	Negligible fire hazard.	
5.3 Advice for firefighters	Fire fighting measures	Move container from fire area if it can be done without risk. Cool containers with water spray until well after the fire is out.
	Protective equipment and precautions for firefighters	Wear self-contained breathing apparatus and protective clothing.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures	Wear personal protective clothing and equipment, see Section 8.
6.2 Environmental precautions	Avoid release to the environment. Do not let the product enter drainage system, surface and ground-water or soil. Contact local authorities in case of environmental release. Do not empty into drains.
6.3 Methods and material for containment and cleaning up	Absorb with sand or other non-combustible material. Collect spilled material in appropriate container for disposal.
6.4 Reference to other sections	See Section 7 for handling procedures. See Section 8 for personal protective equipment recommendations. See Section 13 for disposal considerations.

SECTION 7: Handling and storage

7.1 Precautions for safe handling	Open and handle receptacle with care. Avoid contact with skin and eyes. Wash thoroughly after handling.
7.2 Conditions for safe storage, including any incompatibilities	Store and handle in accordance with all current regulations and standards. Recommended temperature: store at 2-8 °C. Avoid light exposure and keep away from heat sources.
7.3 Specific end use(s)	No additional information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters	Exposure limits	No exposure limit value known.
8.2 Exposure controls	Engineering controls	Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.
	Eye/Face protection	Wear splash resistant safety goggles with a faceshield. Provide an emergency eye wash fountain and quick drench shower in the immediate work area.
	Skin protection	Wear appropriate chemical resistant clothing.
	Glove recommendations	Wear appropriate chemical resistant gloves.
	Respiratory protection	Approved respirators should be worn when airborne concentrations are expected to exceed occupation exposure limits.
	Environmental exposure controls	Avoid any release into the environment.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties	Physical State:	Lyophilized powder
	Colour:	White or Light yellow.
	Odour:	Odourless.
	Odour Threshold:	Not applicable.
	pH:	Not applicable.
	Melting point:	Not available.
	Boiling point:	Not available.
	Flash Point:	Not applicable.
	Evaporation Rate:	Not applicable.
	Flammability (solid, gas):	Not applicable.
	Upper/lower flammability or explosive limits:	Not applicable.
	Vapour Pressure:	Not available.
	Vapour Density:	Not applicable.
	Relative Vapour density:	Not available.
	Solubility(ies):	Not applicable.
	Water Solubility:	Miscible with water.
	Partition coefficient (n-octanol/water) :	Not available.
	Auto-ignition temperature:	Not available.
	Decomposition temperature:	Not available.
	Viscosity:	Not available.
Explosive properties:	Not applicable.	
Oxidising properties:	Not applicable.	
9.2 Other information	No further relevant information available.	

SECTION 10: Stability and reactivity

10.1 Reactivity	No reactivity hazard is expected.
10.2 Chemical stability	The product is stable until the expiration date shown on the box and on the labels when stored at 2 –8 °C.
10.3 Possibility of hazardous reactions	None known.
10.4 Conditions to avoid	None known.
10.5 Incompatible materials	None known.

10.6 Hazardous decomposition products No information available for the product.

SECTION 11: Toxicological information

11.1 Information on toxicological effects	Acute and chronic toxicity	No information available for the product.
	Irritation/corrosivity	No information available for the product.
	Respiratory sensitization	No information available for the product.
	Skin sensitization	No information available for the product.
	Germ cell mutagenicity	No information available for the product.
	Carcinogenicity	No information available for the product.
	Reproductive toxicity	No information available for the product.
	Specific target organ toxicity	No information available for the product.
	Aspiration hazard	No information available for the product.
11.2 Information on other hazards	No further relevant information available.	

SECTION 12: Ecological information

12.1 Toxicity	Not available.	
12.2 Persistence and degradability	Not available.	
12.3 Bioaccumulative potential	Not available.	
12.4 Mobility in soil	Not available.	
12.5 Results of PBT and vPvB assessment	PBT: Not applicable. vPvB: Not applicable.	
12.6 Endocrine disrupting properties	Not available.	
12.7 Other adverse effects	No further relevant information available.	

SECTION 13: Disposal considerations

13.1 Waste treatment methods	Uncleaned packaging	Recommended cleansing agents: Not applicable.
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Waste disposal method	Disposal must be made according to official regulations.
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SECTION 14: Transport information

Transportation	Not regulated as a hazardous material for transportation.
International bulk chemical code	No information available.

SECTION 15: Regulatory information

15.1 Safety, Health and environmental regulations/Legislation specific for the substance or mixture	This safety datasheet complies with the requirements of Regulation (EC) No.1907/2006.
15.2 Chemical safety assessment	No chemical safety assessment has been carried out for the mixture.

SECTION 16: Other information

The information in this document is based on the present state of our knowledge and is applicable to the product, but does not purport to be all inclusive and shall be used only as a guide. It does not represent any guarantee of the properties of the product. However, neither the above named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or 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.

Abbreviations and acronyms	CAS:	Chemical Abstracts Service (division of the American Chemical Society).
	PBT:	Persistent, Bioaccumulative and Toxic.
	vPvB:	very Persistent and very Bioaccumulative.