

Document Type	Technical Document	Security Classification	Secret
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<p>BC-6D 质控物物质安全数据表 (英文版)</p> <p>Safety Data Sheet of BC-6D</p> <p>Control(English)</p>			
Reference Document(s)			
Document No.		Description	
Document dispatch department: (according to the following explanation) 1. Tooling, Fixture, all-purpose & Reagent doc must be filled in. 2. Confidential & Top secret doc. must be filled in, but only for needing to release.		国际体外诊断产品市场部、检验试剂生产部、物流部	

Safety Data Sheet

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

1.1. Product identifier

Product name: Hematology Control.

Model: BC-6D.

Product code: 105-002421-00(High, 4.5mL×6); 105-002422-00(Normal, 4.5mL×6);
105-002423-00(Low, 4.5mL×6); 040-001486-00(Low, 4.5mL×6);
040-001485-00(Normal, 4.5mL×6); 040-001484-00(High, 4.5mL×6);
105-003219-00(High, 4.5mL×1; Normal, 4.5mL×1; Low, 4.5mL×1);
105-002424-00(High, 4.5mL×2; Normal, 4.5mL×2; Low, 4.5mL×2);
040-001487-00(High, 4.5mL×2; Normal, 4.5mL×2; Low, 4.5mL×2).

1.2. Relevant identified uses of the substance or mixture and uses advised against

Intended use: Controls for Hematology. For more information, see instruction for use and labels.

1.3. Details of the supplier of the safety data sheet

Manufacturer: SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD

Address: Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China.

Tel: +86 755 81888998 / Fax: +86 755 26582680

E-mail Address: service@mindray.com

1.4. EC-Representative

EC-Representative: Shanghai International Holding Corp. GmbH(Europe)

Address: Eiffestraße 80, 20537 Hamburg, Germany

Tel: 0049-40-2513175 Fax: 0049-40-255726

1.5. Emergency telephone number

Emergency telephone No: +86 755 81888998 (Mon-Fri; 08:30-18:00 Beijing Time)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

This product is belong to mixture.

This product does not meet the criteria for classification in any hazard class

according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.

2.2. Label elements

Hazard pictograms: Not Applicable.

Signal word: Not Applicable.

Hazard statements: Not Applicable.

Precautionary statements: P501: Dispose of waste product, unused product, contaminated packaging in accordance with governmental requirements.

2.3. Other hazards

PBT, vPvB, carcinogens, mutagens, reproductive toxicants: This product does not contain any known PBT, vPvB, carcinogens, mutagens, reproductive toxicants as listed by SVHC candidate list.

This product was tested by reagents kit using ELISA methods and found non-reactive for Hepatitis B Surface Antigen (HBsAg), antibody to Hepatitis C (HCV), antibody to HIV-1/HIV-2 and antibody to Treponema Pallidum (TP). However, as no testing method can rule out the risk of potential infection with absolute certainty, this product should be handled as a potentially infectious material. In the event of exposure follow the directives of the responsible health authorities.

SECTION 3: Composition/information on ingredients

3.1. Substances

Not Applicable.

3.2. Mixtures

Name	CAS NO.	Concentration
Human or Animal Sourced Material	Not Applicable	5 – 50
Preservatives and Other Non-Hazardous Ingredients	Not Applicable	50 –95
Sodium Azide	26628-22-8	<0.1%

SECTION 4: First aid measures

4.1. Description of first aid measures

Skin contact	If this chemical contacts the skin, flush the area of skin with plenty water. If clothing becomes wet or significantly contaminated, remove and replace clothing. Where there is evidence of skin irritation, get medical attention.
Eye contact	Immediately flush eye(s) with large volumes of water for at

	least 15 minutes, occasionally lifting the lower and upper lids. Get medical attention immediately.
Ingestion	Get medical attention if there has been ingestion of this product. Do not give anything by mouth to an unconscious person. Do not induce vomiting unless directed by medical personnel.
Inhalation	The product is water based with slight volatilization, so there is a very small chance of inhalation. If the product is inhaled, move exposed individual to fresh air, and seek medical assistance immediately.
Medical treatment	Show this safety data sheet to medical personnel. Give symptomatic treatment and supportive therapy.

4.2. Most important symptoms and effects, both acute and delayed

Acute symptoms Not Applicable

Delayed symptoms Not Applicable

4.3. Indication of any immediate medical attention and special treatment needed

Not Applicable

SECTION 5: Firefighting measures

5.1. Extinguishing media

Use fire extinguishing media appropriate for site conditions, such as CO₂, extinguishing powder or water spray.

5.2. Special hazards arising from the substance or mixture

Not applicable

5.3. Advice for firefighters

Fire fighters should wear an approved self-contained breathing apparatus and full protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Wear gloves and laboratory coat. Prevent skin and eye contacting.

6.2. Environmental precautions

Keeping away from drains, surface and ground water and soil.

6.3. Methods and material for containment and cleaning up

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb spill with inert material (e.g. vermiculite, sand or earth) and place in containers suitable for disposal. Avoid generation of aerosols during clean up. Dispose it in accordance with governmental requirements.

6.4. Reference to other sections

See Sections 8 and 13 for more information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid getting this product ON YOU or IN YOU.

Wash hands thoroughly after handling this product. Do not eat, drink, smoke, or apply cosmetics while handling this product. Use in a well-ventilated location. Remove contaminated clothing immediately.

7.2. Conditions for safe storage, including any incompatibilities

All employees who handle this material should be trained to handle it safely.

Avoid contact with eyes, skin, and clothing. Empty containers should be completely drained and disposed of properly. Containers of this product must be properly labeled. Storage areas of this product should be clearly identified, well illuminated, clear of obstruction and accessible only to trained and authorized personnel. Store containers in a cool, dry location away from direct sunlight at temperatures between 2-8°C. Keep product away from freezing. Keep container tightly closed when not in use. Observe all warnings and precautions listed for this product.

7.3. Specific end use(s)

Not Applicable.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Skin protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact.
Eye protection	Safety glasses or chemical goggles should be worn to prevent eye contact.
Respiratory protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels,

the use of respiratory protection should be evaluated by a qualified professional.

Environmental exposure controls	Prevent the product from entering drains and watercourses.
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8.2. Exposure controls

Follow the usual biosafety practices for handling potentially infectious materials. Use in well ventilated area. Keep away from foodstuffs, beverages and feed. Remove all soiled and contaminated clothing immediately. Wash hands before breaks and at the end of work.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Red Liquid.
Odour	Little to none.
Odour threshold	Not applicable.
pH	Neutra.
Melting point/freezing point	No information available.
Initial boiling point and boiling range	No information available.
Flash point (typical)	Not applicable.
Evaporation rate	Not applicable.
Flammability (solid, gas)	Not applicable. The product is water based, and not flammable or explosive.
Upper/lower flammability or explosive limits	Not applicable. The product is water based, and not flammable or explosive.
Vapour pressure	Not applicable.
Vapour density	Not applicable.
Relative density	No information available.
Solubility(ies)	Fully miscible in water.
Partition coefficient: n-octanol/water	Not applicable.
Auto-ignition	Not applicable. The product is water based, and not

temperature	flammable or explosive.
Decomposition temperature	Not applicable.
Viscosity	No information available.
Explosive properties	Not applicable. The product is water based, and not flammable or explosive.
Oxidizing properties	Not applicable.

9.2. Other information

No information available.

SECTION 10: Stability and reactivity

10.1. Reactivity

This product contains low concentrations of Sodium Azide <0.1% (w/w). Sodium Azide can form explosive compounds with heavy metals which, with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.2. Chemical stability

This product is stable under conditions specified by instruction for use and labels.

10.3. Possibility of hazardous reactions

Not applicable.

10.4. Conditions to avoid

Avoid Frozen and high temperature(above 8°C). Keep away from sunlight.

10.5. Incompatible materials

Metals and metallic compounds.

10.6. Hazardous decomposition products

When stored as labeled, no known hazardous decomposition products are formed during the shelf-life of this product.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Toxicokinetics, metabolism and distribution	No experimental data for this preparation available.
Acute toxicity	No experimental data for this preparation available.

Skin corrosion/irritation	No experimental data for this preparation available.
Serious eye Damage/irritation	No experimental data for this preparation available.
Respiratory or skin Sensitisation	No experimental data for this preparation available.
Germ cell mutagenicity	No experimental data for this preparation available.
Carcinogenicity	No experimental data for this preparation available.
Reproductive toxicity	No experimental data for this preparation available.
STOT-single exposure	No experimental data for this preparation available.
STOT-repeated exposure	No experimental data for this preparation available.
Aspiration hazard	No experimental data for this preparation available.

SECTION 12: Ecological information

12.1. Toxicity

Not applicable.

12.2. Persistence and degradability

Not applicable.

12.3. Bioaccumulative potential

Not applicable.

12.4. Mobility in soil

Not applicable.

12.5. Results of PBT and vPvB assessment

Not applicable.

12.6. Other adverse effects

Not applicable.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Dispose of waste product, unused product and contaminated packaging in accordance with local requirements. To ensure compliance we recommend that you contact the relevant(local) authorities and/or an approved waste-disposal company for information.

SECTION 14: Transport information

14.1. UN number

IATA, ICAO, IMDG, ADR, RID, ADN	Not regulated
14.2. UN proper shipping name	
IATA, ICAO, IMDG, ADR, RID, ADN	Not regulated
14.3. Transport hazard class(es)	
IATA, ICAO, IMDG, ADR, RID, ADN	Not regulated
14.4. Packing group	
IATA, ICAO, IMDG, ADR, RID, ADN	Not regulated
14.5. Environmental hazards	

This product is not designated as a marine pollutant by the Department of Transportation.

14.6. Special precautions for user

See chapter 7 and chapter 8 for information.

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulations: This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

US Federal and State Regulations:

CERCLA/SARA 302: Sodium Azide is listed.

CERCLA/SARA 304: Sodium Azide is listed.

SARA 313: Sodium Azide is listed.

TSCA (Toxic Substances Control Act): Sodium Azide is listed.

Canada: This product is exempt from WHMIS requirements.

15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

SECTION 16: Other information

Date of last revision(year/month/day): 2016/03/03 Replaces edition of 3.0

Information of this Safety Data Sheet represents the today's state of our knowledge.

The purpose is to characterise the product regarding safety precautions having to be kept. This document will not be a certification of features and will not be the basis of a legal contract.

The primary changes in 4.0 as follows:

1. Complementing the related transport regulation.