

艾博生物医药 ABON Bio	质量体系技术规范 Quality System Technical Specification	艾博文件编号: MS-0218
		Agile 文件编号: MS-0218
文件名称 Document Name: Safety Data Sheet MONO Rapid Test Device (Whole Blood/ Serum/ Plasma) (ABON)		
Version: AC		Page 1 of 26

发放号 Distribution No:
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## SAFETY DATA SHEET

### MONO Rapid Test Device (Whole Blood/Serum/Plasma) (ABON)

According to Regulation (EC) No. 1907/2006

This document contains SDS for the following kit components.

Device  
Whole blood buffer  
Negative control  
Positive control

#### Section 1 Identification of the substance/mixture and of the company/undertaking

##### 1.1 Product identifier:

**MONO Rapid Test Device**

Identification on the label/Trade name:

**(Whole Blood/Serum/Plasma)**

Additional identification:

**Reference No.: IMO-402**

Identification of the product:

See section 3

Index Number:

Not available

REACH registration No.:

Not available

##### 1.2 Relevant identified uses of the substance and uses advised against:

###### 1.2.1 Identified uses:

In vitro diagnostic reagent. For professional use only.

###### 1.2.2 Uses advised against:

Not available.

##### 1.3 Details of the supplier of the safety data sheet:

Supplier(Manufacturer):

Abon Biopharm (Hangzhou) Co., Ltd

Address:

#198 12<sup>th</sup> Street East, Hangzhou Economic & Technological  
Development Area, Hangzhou, 310018, P.R.China

Contact person(E-mail):

abon.intelra@alere.com

Telephone:

+ 86-571-81638052

Fax:

+ 86-571-81638001

##### 1.4 Emergency telephone Number:

+86-571-81638052

Available outside office hours?

YES

NO

#### Section 2 Hazards Identification

##### 2.1 Classification of the substance/mixture:

###### 2.1.1 Classification:

The mixture is classified as following according to 1999/45/EC and REGULATION (EC) No 1272/2008:

艾博生物医药 ABON Bio	质量体系技术规范 Quality System Technical Specification	艾博文件编号: MS-0218
		Agile 文件编号: MS-0218
文件名称 Document Name: Safety Data Sheet MONO Rapid Test Device (Whole Blood/ Serum/ Plasma) (ABON)		
Version: AC		Page 2 of 26

<b>REGULATION (EC) No 1272/2008</b>	
Hazard classes/Hazard categories	Hazard codes
N/A	N/A

For full text of H- phrases: see section 2.2.

<b>1999/45/EC</b>	
Hazards characteristics	R-Phrases
N/A	N/A

For full text of R- phrases: see section 16.

## 2.2 label elements:

<b>Hazard Pictograms:</b>	No hazard pictogram is used.
<b>Signal Word(S):</b>	No signal word is used.
<b>Hazard Statement:</b>	Not applicable.
<b>Precautionary statement:</b>	Not applicable.

## 2.3 Other hazards:

Not available.

## Section 3 Composition/information on ingredients

<b>Substance/Mixture:</b>	Mixture
<b>Description:</b>	In vitro diagnostic reagent test device. Preparation. Laminated test strip consisting of solid support materials impregnated with dried chemical / biochemical reagents.

### Ingredient(s):

Chemical Name	Registration No.	CAS No.	EC No.	Concentration	Classification
Ethylenediamine, ethoxylated propoxylated and	-	26316-40-5	500-047-1	0.267%	H317 H319

**Additional Information:** Each strip/device is packaged in a foil pouch.

## Section 4 First aid measures

### 4.1 Description of first aid measures:

The following first aid measures are only relevant in the event of serious misuse, whereby the device is disassembled and there is exposure to the chemicals in the test strip. In all cases of doubt, or when symptoms persist, seek medical attention.

#### 4.1.1 In case of inhalation:

If inhalation, remove victim to fresh air and keep at rest in a position comfortable for breathing. If you feel unwell, seek medical attention.

#### 4.1.2 In case of skin contact:

Wash thoroughly with soap and water. Get medical attention in the unlikely event that irritation persists.

#### 4.1.3 In case of eyes contact:

Flush with running water for at least 15 minutes. If irritation persists get medical attention.

艾博生物医药 ABON Bio	质量体系技术规范 Quality System Technical Specification	艾博文件编号: MS-0218
		Agile 文件编号: MS-0218
文件名称 Document Name: Safety Data Sheet MONO Rapid Test Device (Whole Blood/ Serum/ Plasma) (ABON)		
Version: AC	Page 3 of 26	

**4.1.4 In case of ingestion:**

Rinse mouth with water. Obtain medical attention if symptoms occur.

**4.2 Most important symptoms and effects, both acute and delayed:**

The product is not classified as harmful to human health effect.

**4.3 Indication of any immediate medical attention and special treatment needed:**

If skin irritation or rash occurs, get medical advice/attention.

**Section 5 Fire-Fighting measures****5.1 Extinguishing media:**

**Suitable extinguishing media:** Use extinguishing agents appropriate for surrounding fire.

**Unsuitable extinguishing media:** Not available.

**5.2 Special hazards arising from the substance or mixture**

In case of fire, the following can be released: carbon monoxide, carbon dioxide.

**5.3 Special fire fighting methods and special protective actions for fire-fighters:**

Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

**Section 6 Accidental release measures****6.1 Personal precautions, protective equipment and emergency procedures:**

**6.1.1 For non-emergency personnel:** Provide adequate ventilation. Avoid inhalation of dust. Avoid skin and eye contact. Refer to section 8 of SDS for personal protection details.

**6.1.2 For emergency responders:** Wear an appropriate NIOSH/MSHA approved respirator if dust is generated.

**6.2 Environmental Precautions:**

Do not allow material to be released to the environment without proper governmental permits.

**6.3 Methods for Containment and Cleaning up:**

Take up mechanically.

**6.4 Reference to other sections:**

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for information on disposal.

**6.5 Additional information:**

Not applicable.

**Section 7 Handling and storage****7.1 Precautions for safe handling:**

**7.1.1 Protective measures:** Good hygienic practices should be observed. Avoid contact with skin and eyes. Avoid breathing dust. If exposed to high dust concentration, leave area immediately. Work clothes should be washed separately at the end of each work day. Keep away from sources of ignition. Ensure good ventilation/exhaustion at the workplace. Specimens should be handled as potentially infectious materials. Refer to Directive 2000/54/EC for information on handling biohazardous materials. Clean work areas with hypochlorite or other disinfecting agent.

**7.1.2 Advice on general occupational hygiene:** Do not eat, drink and smoke in work areas. Wash hands after use. Remove contaminated clothing and protective equipment before entering

艾博生物医药 ABON Bio	质量体系技术规范 Quality System Technical Specification	艾博文件编号: MS-0218
		Agile 文件编号: MS-0218
文件名称 Document Name: Safety Data Sheet MONO Rapid Test Device (Whole Blood/ Serum/ Plasma) (ABON)		
Version: AC		Page 4 of 26

- 7.2 Conditions for safe storage, including any incompatibilities: eating areas. Material should be stored in a clean, dry environment at 2 to 30°C in original packaging and not exposed to ignition sources.
- 7.3 Specific end use(s): Use as per instructions for use.

## Section 8 Exposure Controls/Personal Protection

### 8.1 Control parameters:

- 8.1.1 Occupational exposure limits: Not available.
- 8.1.2 Additional exposure limits under the conditions of use: Not available.
- 8.1.3 DNEL/DMEL and PNEC-Values: Not available.

### 8.2 Exposure controls:

- 8.2.1 Appropriate engineering controls: If user operations generate dust, use ventilation to keep exposure to airborne contaminants below the exposure limit.
- 8.2.2 Individual protection measures, such as personal protective equipment:
- Eye/face protection: No special protective equipment required.
- Hand protection: No special protective equipment required.
- Body protection: No special protective equipment required.
- Respiratory protection: No special protective equipment required.
- Thermal hazards: No special protective equipment required.
- 8.2.3 Environmental exposure controls: Avoid discharge into the environment. According to local regulations, Federal and official regulations.

## Section 9 Physical and chemical properties

### 9.1 Information on basic physical and chemical properties:

- Appearance: Laminated test strip consisting of solid support materials impregnated with dried chemical / biochemical reagents. The test strip is housed in a plastic cassette.
- Colour: White.
- Odour: No odour.
- Odour threshold: Not available
- pH: Not available
- Melting point/range (°C): < -150 °C (CAS#26316-40-5)
- Boiling point/range (°C): Not available
- Flash point (°C): > 250 °C (CAS#26316-40-5)
- Evaporation rate: Not available
- Flammability limit - lower (%): Not available
- Flammability (solid, gas): Not available
- Ignition temperature (°C): Not available
- Upper/lower flammability/explosive limits: Not available
- Vapour pressure (20°C): Not available
- Vapour density: Not available
- Relative Density: 1.06 at 20 °C (CAS#26316-40-5)

艾博生物医药 ABON Bio	质量体系技术规范 Quality System Technical Specification	艾博文件编号: MS-0218
		Agile 文件编号: MS-0218
文件名称 Document Name: Safety Data Sheet MONO Rapid Test Device (Whole Blood/ Serum/ Plasma) (ABON)		
Version: AC		Page 5 of 26

<b>Bulk density (kg/m<sup>3</sup>):</b>	Not available
<b>Water solubility (g/l):</b>	Not available
<b>n-Octanol/Water (log Po/w):</b>	Not available
<b>Auto-ignition temperature:</b>	305 °C (CAS#26316-40-5)
<b>Decomposition temperature:</b>	235 °C (CAS#26316-40-5)
<b>Viscosity, dynamic (mPa.s):</b>	Not available
<b>Explosive properties:</b>	Not available
<b>Oxidising properties:</b>	Not available
<b>Molecular Formula:</b>	Not available
<b>Molecular Weight:</b>	Not available

**9.2. Other information:**

<b>Fat solubility(solvent– oil to be specified)</b>	Not available
<b>etc:</b>	
<b>Surface tension:</b>	63.17 mN/m at 20 °C (CAS#26316-40-5)
<b>Dissociation constant in water( pKa):</b>	Not available
<b>Oxidation-reduction Potential:</b>	Not available
<b>Specific gravity:</b>	Not available

**Section 10 Stability and reactivity**

<b>10.1 Reactivity:</b>	The substance is stable under normal storage and handling conditions.
<b>10.2 Chemical stability:</b>	Stable at 2 to 30°C in closed containers under normal storage and handling conditions.
<b>10.3 Possibility of hazardous reactions:</b>	No dangerous reactions known.
<b>10.4 Conditions to avoid:</b>	Incompatible materials.
<b>10.5 Incompatible materials:</b>	Strong oxidizing agents, strong acids.
<b>10.6 Hazardous decomposition products:</b>	Carbon monoxide, carbon dioxide.

**Section 11 Toxicological information****11.1 Toxicokinetics, metabolism and distribution:**

<b>Non-human toxikological data:</b>	Not available
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**11.2 Information on toxicological effects:**

**Acute toxicity:** Ethylenediamine, ethoxylated and propoxylated (CAS#26316-40-5)

<b>LD50(Oral, Rat):</b>	> 5000 mg/kg bw
<b>LD50(Dermal, Rabbit):</b>	> 5000 mg/kg bw
<b>LC50(Inhalation, Rat):</b>	Not available
<b>Skin corrosion/Irritation:</b>	Not classified
<b>Serious eye damage/irritation:</b>	Not classified
<b>Respiratory or skin sensitization:</b>	Not classified
<b>Germ cell mutagenicity:</b>	Not classified
<b>Carcinogenicity:</b>	Not classified
<b>Reproductive toxicity:</b>	Not classified
<b>STOT- single exposure:</b>	Not classified

艾博生物医药 ABON Bio	质量体系技术规范 Quality System Technical Specification	艾博文件编号: MS-0218
		Agile 文件编号: MS-0218
文件名称 Document Name: Safety Data Sheet MONO Rapid Test Device (Whole Blood/ Serum/ Plasma) (ABON)		
Version: AC		Page 6 of 26

STOT-repeated exposure: Not classified

## Section 12 Ecological information

**Toxicity:** Ethylenediamine, ethoxylated and propoxylated (CAS#26316-40-5)

Acute toxicity		Time	Species	Method	Evaluation	Remarks
LC50	25600 mg/L	96h	Fish	OECD 203	N/A	N/A
EC50	103 mg/L	24h	Daphnia	OECD 202	N/A	N/A
EC50	N/A	72h	Algae	OECD 201	N/A	N/A

**Persistence and degradability:** Not available.  
**Bioaccumulative potential:** Not available.  
**Mobility in soil:** Not available.  
**Results of PBT&vPvB assessment:** Not available.  
**Other adverse effects:** Not available.

## Section 13 Disposal considerations

**13.1 Waste treatment methods:** The material should be disposed of by incineration in a chemical incinerator in compliance with national and regional requirements.

**13.2 Product / Packaging disposal:** If empty container retains product residues, all label precautions must be observed. Dispose according to national or local regulations.

## Section 14 Transport information

	Land transport(ADR/RID)	Sea transport (IMDG)	Air transport (ICAO/IATA)
UN-Number	Not regulated	Not regulated	Not regulated
UN Proper shipping name	Not regulated	Not regulated	Not regulated
Transport hazard Class	Not regulated	Not regulated	Not regulated
Packaging group	Not regulated	Not regulated	Not regulated
Environmental hazards	No	No	No
Special precautions for user	See section 2.2	See section 2.2	See section 2.2
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not regulated	Not regulated	Not regulated

## Section 15 Regulation information

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

**Relevant information regarding authorization:** Not applicable.  
**Relevant information regarding restriction:** Not applicable.  
**Other EU regulations:** In Vitro diagnostics medical devices directive 98/79/EC.  
**Other National regulations:** Not applicable

艾博生物医药 ABON Bio	质量体系技术规范 Quality System Technical Specification	艾博文件编号: MS-0218
		Agile 文件编号: MS-0218
文件名称 Document Name: Safety Data Sheet MONO Rapid Test Device (Whole Blood/ Serum/ Plasma) (ABON)		
Version: AC		Page 7 of 26

Chemical Safety Assessment has been carried out? YES  NO

### Section 16 Other information

#### 16.1 Indication of changes:

Version 1.0 Amended by EU No 453/2010

#### 16.2 Relevant R- phrases (number and full text):

Not applicable.

#### 16.3 Training instructions:

Not applicable.

#### 16.4 Further information:

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.

#### 16.5 Notice to reader:

Employers should use this information only as a supplement to other information gathered by them, and should make independent judgment of suitability of this information to ensure proper use and protect the health and safety of employees. This information is furnished without warranty, and any use of the product not in conformance with this Safety Data Sheet, or in combination with any other product or process, is the responsibility of the user.

艾博生物医药 ABON Bio	质量体系技术规范 Quality System Technical Specification	艾博文件编号: MS-0218
		Agile 文件编号: MS-0218
文件名称 Document Name: Safety Data Sheet MONO Rapid Test Device (Whole Blood/ Serum/ Plasma) (ABON)		
Version: AC		Page 8 of 26

## Section 1 Identification of the substance/mixture and of the company/undertaking

### 1.1 Product identifier:

Identification on the label/Trade name: **Whole blood buffer of MONO Rapid Test Device (Whole Blood/Serum/Plasma)**

Additional identification: **Reference No.: IMO-402**

Identification of the product: See section 3

Index Number: Not available

REACH registration No.: Not available

### 1.2 Relevant identified uses of the substance and uses advised against:

#### 1.2.1 Identified uses:

In vitro diagnostic reagent. For professional use only.

#### 1.2.2 Uses advised against:

Not available.

### 1.3 Details of the supplier of the safety data sheet:

Supplier(Manufacturer): Abon Biopharm (Hangzhou) Co., Ltd  
 Address: #198 12<sup>th</sup> Street East, Hangzhou Economic & Technological Development Area, Hangzhou, 310018, P.R.China  
 Contact person(E-mail): abon.intelra@alere.com  
 Telephone: + 86-571-81638052  
 Fax: + 86-571-81638001

### 1.4 Emergency telephone Number:

+86-571-81638052

Available outside office hours? YES  NO

## Section 2 Hazards Identification

### 2.1 Classification of the substance/mixture:

#### 2.1.1 Classification:

The mixture is classified as following according to 1999/45/EC and REGULATION (EC) No 1272/2008:

REGULATION (EC) No 1272/2008	
Hazard classes/Hazard categories	Hazard codes
N/A	N/A

For full text of H- phrases: see section 2.2.

1999/45/EC	
Hazards characteristics	R-Phrases
N/A	N/A

For full text of R- phrases: see section 16.

### 2.2 label elements:

Hazard Pictograms: No hazard pictogram is used.

Signal Word(S): No signal word is used.



艾博生物医药 ABON Bio	质量体系技术规范 Quality System Technical Specification	艾博文件编号: MS-0218
		Agile 文件编号: MS-0218
文件名称 Document Name: Safety Data Sheet MONO Rapid Test Device (Whole Blood/ Serum/ Plasma) (ABON)		
Version: AC		Page 9 of 26

**Hazard Statement:** Not applicable.

**Precautionary statement:** Not applicable.

### 2.3 Other hazards:

Not available.

## Section 3 Composition/information on ingredients

**Substance/Mixture:** Mixture

### Ingredient(s):

Chemical Name	Registration No.	CAS No.	EC No.	Concentration	Classification
Sodium Azide	-	26628-22-8	247-852-1	0.09%	H300 H400 H410
Kanamycin Sulfate	-	25389-94-0	246-933-9	0.025%	H360

## Section 4 First aid measures

### 4.1 Description of first aid measures:

In all cases of doubt, or when symptoms persist, seek medical attention.

#### 4.1.1 In case of inhalation:

If inhalation, remove victim to fresh air and keep at rest in a position comfortable for breathing. If you feel unwell, seek medical attention.

#### 4.1.2 In case of skin contact:

Wash thoroughly with soap and water. Get medical attention in the unlikely event that irritation persists.

#### 4.1.3 In case of eyes contact:

Flush with running water for at least 15 minutes. If irritation persists get medical attention.

#### 4.1.4 In case of ingestion:

Rinse mouth with water. Obtain medical attention if symptoms occur.

### 4.2 Most important symptoms and effects, both acute and delayed:

The product is not classified as harmful to human health effect.

### 4.3 Indication of any immediate medical attention and special treatment needed:

If skin irritation or rash occurs, get medical advice/attention.

## Section 5 Fire-Fighting measures

### 5.1 Extinguishing media:

**Suitable extinguishing media:** Use extinguishing agents appropriate for surrounding fire.

**Unsuitable extinguishing media:** Not available.

### 5.2 Special hazards arising from the substance or mixture

In case of fire, the following can be released: carbon monoxide, carbon dioxide.

### 5.3 Special fire fighting methods and special protective actions for fire-fighters:

Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

艾博生物医药 ABON Bio	质量体系技术规范 Quality System Technical Specification	艾博文件编号: MS-0218
		Agile 文件编号: MS-0218
文件名称 Document Name: Safety Data Sheet MONO Rapid Test Device (Whole Blood/ Serum/ Plasma) (ABON)		
Version: AC		Page 10 of 26

## Section 6 Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures:

6.1.1 For non-emergency personnel: Provide adequate ventilation. Avoid inhalation of vapours. Avoid skin and eye contact. Refer to section 8 of SDS for personal protection details.

6.1.2 For emergency responders: Wear an appropriate NIOSH/MSHA approved respirator if vapour is generated.

6.2 Environmental Precautions: Do not allow material to be released to the environment without proper governmental permits.

6.3 Methods for Containment and Cleaning up: Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Ensure adequate ventilation.

6.4 Reference to other sections: See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for information on disposal.

6.5 Additional information: Not applicable.

## Section 7 Handling and storage

### 7.1 Precautions for safe handling:

7.1.1 Protective measures: Good hygienic practices should be observed. Avoid contact with skin and eyes. Avoid breathing vapours. Work clothes should be washed separately at the end of each work day. Keep away from sources of ignition. Ensure good ventilation/exhaustion at the workplace.

7.1.2 Advice on general occupational hygiene: Do not eat, drink and smoke in work areas. Wash hands after use. Remove contaminated clothing and protective equipment before entering eating areas.

7.2 Conditions for safe storage, including any incompatibilities: Material should be stored in a clean, dry environment at 2 to 30°C in original packaging and not exposed to ignition sources.

7.3 Specific end use(s): Use as per instructions for use.

## Section 8 Exposure Controls/Personal Protection

### 8.1 Control parameters:

8.1.1 Occupational exposure limits: Not available.

8.1.2 Additional exposure limits under the conditions of use: Not available.

8.1.3 DNEL/DMEL and PNEC-Values: Not available.

### 8.2 Exposure controls:

8.2.1 Appropriate engineering controls: Use adequate ventilation to keep airborne concentrations low.

#### 8.2.2 Individual protection measures, such as personal protective equipment:

Eye/face protection: No special protective equipment required.

Hand protection: No special protective equipment required.

Body protection: No special protective equipment required.

Respiratory protection: No special protective equipment required.

Thermal hazards: No special protective equipment required.

8.2.3 Environmental exposure controls: Avoid discharge into the environment. According to local regulations, Federal and official regulations.

艾博生物医药 ABON Bio	质量体系技术规范 Quality System Technical Specification	艾博文件编号: MS-0218
		Agile 文件编号: MS-0218
文件名称 Document Name: Safety Data Sheet MONO Rapid Test Device (Whole Blood/ Serum/ Plasma) (ABON)		
Version: AC		Page 11 of 26

## Section 9 Physical and chemical properties

### 9.1 Information on basic physical and chemical properties:

Appearance:	Liquid
Colour:	Colorless
Odour:	Odorless
Odour threshold:	Not available
pH:	Not available
Melting point/range (°C):	Not available
Boiling point/range (°C):	Not available
Flash point (°C):	Not available
Evaporation rate:	Not available
Flammability limit - lower (%):	Not available
Flammability (solid, gas):	Not available
Ignition temperature (°C):	Not available
Upper/lower flammability/explosive limits:	Not available
Vapour pressure (20°C):	Not available
Vapour density:	Not available
Relative Density:	Not available
Bulk density (kg/m <sup>3</sup> ):	Not available
Water solubility (g/l):	Not available
n-Octanol/Water (log Po/w):	Not available
Auto-ignition temperature:	Not available
Decomposition temperature:	Not available
Viscosity, dynamic (mPa.s):	Not available
Explosive properties:	Not available
Oxidising properties:	Not available
Molecular Formula:	Not available
Molecular Weight:	Not available

### 9.2. Other information:

Fat solubility(solvent– oil to be specified) etc:	Not available
Surface tension:	Not available
Dissociation constant in water( pKa):	Not available
Oxidation-reduction Potential:	Not available
Specific gravity:	Not available

## Section 10 Stability and reactivity

10.1 Reactivity:	The substance is stable under normal storage and handling conditions.
10.2 Chemical stability:	Stable at 2 to 30°C in closed containers under normal storage and handling conditions.

艾博生物医药 ABON Bio	质量体系技术规范 Quality System Technical Specification	艾博文件编号: MS-0218
		Agile 文件编号: MS-0218
文件名称 Document Name: Safety Data Sheet MONO Rapid Test Device (Whole Blood/ Serum/ Plasma) (ABON)		
Version: AC		Page 12 of 26

<b>10.3 Possibility of hazardous reactions:</b>	No dangerous reactions known.
<b>10.4 Conditions to avoid:</b>	Incompatible materials.
<b>10.5 Incompatible materials:</b>	Strong oxidizing agents, strong acids.
<b>10.6 Hazardous decomposition products:</b>	Carbon monoxide, carbon dioxide.

### Section 11 Toxicological information

#### 11.1 Toxicokinetics, metabolism and distribution:

Non-human toxicological data: Not available

#### 11.2 Information on toxicological effects:

##### Acute toxicity:

LD50(Oral, Rat): Not available

LD50(Dermal, Rabbit): Not available

LC50(Inhalation, Rat): Not available

Skin corrosion/Irritation: Not classified

Serious eye damage/irritation: Not classified

Respiratory or skin sensitization: Not classified

Germ cell mutagenicity: Not classified

Carcinogenicity: Not classified

Reproductive toxicity: Not classified

STOT- single exposure: Not classified

STOT-repeated exposure: Not classified

### Section 12 Ecological information

#### Toxicity:

Acute toxicity		Time	Species	Method	Evaluation	Remarks
LC50	N/A	96h	Fish	OECD 203	N/A	N/A
EC50	N/A	48h	Daphnia	OECD 202	N/A	N/A
EC50	N/A	72h	Algae	OECD 201	N/A	N/A

Persistence and degradability: Not available.

Bioaccumulative potential: Not available.

Mobility in soil: Not available.

Results of PBT&vPvB assessment: Not available.

Other adverse effects: Not available.

### Section 13 Disposal considerations

**13.1 Waste treatment methods:** The material should be disposed of by incineration in a chemical incinerator in compliance with national and regional requirements.

**13.2 Product / Packaging disposal:** If empty container retains product residues, all label precautions must be observed. Dispose according to national or local regulations.

### Section 14 Transport information

艾博生物医药 ABON Bio	质量体系技术规范 Quality System Technical Specification	艾博文件编号: MS-0218
		Agile 文件编号: MS-0218
文件名称 Document Name: Safety Data Sheet MONO Rapid Test Device (Whole Blood/ Serum/ Plasma) (ABON)		
Version: AC		Page 13 of 26

	Land transport(ADR/RID)	Sea transport (IMDG)	Air transport (ICAO/IATA)
UN-Number	Not regulated	Not regulated	Not regulated
UN Proper shipping name	Not regulated	Not regulated	Not regulated
Transport hazard Class	Not regulated	Not regulated	Not regulated
Packaging group	Not regulated	Not regulated	Not regulated
Environmental hazards	No	No	No
Special precautions for user	See section 2.2	See section 2.2	See section 2.2
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not regulated	Not regulated	Not regulated

### Section 15 Regulation information

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

Relevant information regarding authorization:	Not applicable.
Relevant information regarding restriction:	Not applicable.
Other EU regulations:	In Vitro diagnostics medical devices directive 98/79/EC.
Other National regulations:	Not applicable
Chemical Safety Assessment has been carried out?	YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>

### Section 16 Other information

#### 16.1 Indication of changes:

Version 1.0 Amended by EU No 453/2010

#### 16.2 Relevant R- phrases (number and full text):

Not applicable.

#### 16.3 Training instructions:

Not applicable.

#### 16.4 Further information:

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.

#### 16.5 Notice to reader:

Employers should use this information only as a supplement to other information gathered by them, and should make independent judgment of suitability of this information to ensure proper use and protect the health and safety of employees. This information is furnished without warranty, and any use of the product not in conformance with this Safety Data Sheet, or in combination with any other product or process, is the responsibility of the user.

艾博生物医药 ABON Bio	质量体系技术规范 Quality System Technical Specification	艾博文件编号: MS-0218
		Agile 文件编号: MS-0218
文件名称 Document Name: Safety Data Sheet MONO Rapid Test Device (Whole Blood/ Serum/ Plasma) (ABON)		
Version: AC		Page 14 of 26

## Section 1 Identification of the substance/mixture and of the company/undertaking

### 1.1 Product identifier:

Identification on the label/Trade name:

**Negative control of MONO Rapid Test  
Device (Whole Blood/Serum/Plasma)**

Additional identification:

**Reference No.: IMO-402**

Identification of the product:

See section 3

Index Number:

Not available

REACH registration No.:

Not available

### 1.2 Relevant identified uses of the substance and uses advised against:

#### 1.2.1 Identified uses:

In vitro diagnostic reagent. For professional use only.

#### 1.2.2 Uses advised against:

Not available.

### 1.3 Details of the supplier of the safety data sheet:

Supplier(Manufacturer):

Abon Biopharm (Hangzhou) Co., Ltd

Address:

#198 12<sup>th</sup> Street East, Hangzhou Economic & Technological  
Development Area, Hangzhou, 310018, P.R.China

Contact person(E-mail):

abon.intelra@alere.com

Telephone:

+ 86-571-81638052

Fax:

+ 86-571-81638001

### 1.4 Emergency telephone Number:

+86-571-81638052

Available outside office hours?

YES

NO

## Section 2 Hazards Identification

### 2.1 Classification of the substance/mixture:

#### 2.1.1 Classification:

The mixture is classified as following according to 1999/45/EC and REGULATION (EC) No 1272/2008:

REGULATION (EC) No 1272/2008	
Hazard classes/Hazard categories	Hazard codes
N/A	N/A

For full text of H- phrases: see section 2.2.

1999/45/EC	
Hazards characteristics	R-Phrases
N/A	N/A

For full text of R- phrases: see section 16.

### 2.2 label elements:

Hazard Pictograms:

No hazard pictogram is used.

艾博生物医药 ABON Bio	质量体系技术规范 Quality System Technical Specification	艾博文件编号: MS-0218
		Agile 文件编号: MS-0218
文件名称 Document Name: Safety Data Sheet MONO Rapid Test Device (Whole Blood/ Serum/ Plasma) (ABON)		
Version: AC		Page 15 of 26

**Signal Word(S):** No signal word is used.

**Hazard Statement:** Not applicable.

**Precautionary statement:** Not applicable.

### 2.3 Other hazards:

Not available.

## Section 3 Composition/information on ingredients

**Substance/Mixture:** Mixture

**Ingredient(s):**

Chemical Name	Registration No.	CAS No.	EC No.	Concentration	Classification
BSA	-	9048-46-8	232-936-2	0.5%	H302
Sodium Azide	-	26628-22-8	247-852-1	0.09%	H300 H400 H410

## Section 4 First aid measures

### 4.1 Description of first aid measures:

In all cases of doubt, or when symptoms persist, seek medical attention.

#### 4.1.1 In case of inhalation:

If inhalation, remove victim to fresh air and keep at rest in a position comfortable for breathing. If you feel unwell, seek medical attention.

#### 4.1.2 In case of skin contact:

Wash thoroughly with soap and water. Get medical attention in the unlikely event that irritation persists.

#### 4.1.3 In case of eyes contact:

Flush with running water for at least 15 minutes. If irritation persists get medical attention.

#### 4.1.4 In case of ingestion:

Rinse mouth with water. Obtain medical attention if symptoms occur.

### 4.2 Most important symptoms and effects, both acute and delayed:

The product is not classified as harmful to human health effect.

### 4.3 Indication of any immediate medical attention and special treatment needed:

If skin irritation or rash occurs, get medical advice/attention.

## Section 5 Fire-Fighting measures

### 5.1 Extinguishing media:

**Suitable extinguishing media:** Use extinguishing agents appropriate for surrounding fire.

**Unsuitable extinguishing media:** Not available.

### 5.2 Special hazards arising from the substance or mixture

In case of fire, the following can be released: carbon monoxide, carbon dioxide.

### 5.3 Special fire fighting methods and special protective actions for fire-fighters:

Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

艾博生物医药 ABON Bio	质量体系技术规范 Quality System Technical Specification	艾博文件编号: MS-0218
		Agile 文件编号: MS-0218
文件名称 Document Name: Safety Data Sheet MONO Rapid Test Device (Whole Blood/ Serum/ Plasma) (ABON)		
Version: AC		Page 16 of 26

## Section 6 Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures:

**6.1.1 For non-emergency personnel:** Provide adequate ventilation. Avoid inhalation of vapours. Avoid skin and eye contact. Refer to section 8 of SDS for personal protection details.

**6.1.2 For emergency responders:** Wear an appropriate NIOSH/MSHA approved respirator if vapour is generated.

**6.2 Environmental Precautions:** Do not allow material to be released to the environment without proper governmental permits.

**6.3 Methods for Containment and Cleaning up:** Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Ensure adequate ventilation.

**6.4 Reference to other sections:** See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.

See Section 13 for information on disposal.

**6.5 Additional information:** Not applicable.

## Section 7 Handling and storage

### 7.1 Precautions for safe handling:

**7.1.1 Protective measures:** Good hygienic practices should be observed. Avoid contact with skin and eyes. Avoid breathing vapours. Work clothes should be washed separately at the end of each work day. Keep away from sources of ignition. Ensure good ventilation/exhaustion at the workplace.

**7.1.2 Advice on general occupational hygiene:** Do not eat, drink and smoke in work areas. Wash hands after use. Remove contaminated clothing and protective equipment before entering eating areas.

**7.2 Conditions for safe storage, including any incompatibilities:** Material should be stored in a clean, dry environment at 2 to 30°C in original packaging and not exposed to ignition sources.

**7.3 Specific end use(s):** Use as per instructions for use.

## Section 8 Exposure Controls/Personal Protection

### 8.1 Control parameters:

**8.1.1 Occupational exposure limits:** Not available.

**8.1.2 Additional exposure limits under the conditions of use:** Not available.

**8.1.3 DNEL/DMEL and PNEC-Values:** Not available.

### 8.2 Exposure controls:

**8.2.1 Appropriate engineering controls:** Use adequate ventilation to keep airborne concentrations low.

#### 8.2.2 Individual protection measures, such as personal protective equipment:

**Eye/face protection:** No special protective equipment required.

**Hand protection:** No special protective equipment required.

**Body protection:** No special protective equipment required.

**Respiratory protection:** No special protective equipment required.

**Thermal hazards:** No special protective equipment required.

**8.2.3 Environmental exposure controls:** Avoid discharge into the environment. According to local regulations,



艾博生物医药 ABON Bio	质量体系技术规范 Quality System Technical Specification	艾博文件编号: MS-0218
		Agile 文件编号: MS-0218
文件名称 Document Name: Safety Data Sheet MONO Rapid Test Device (Whole Blood/ Serum/ Plasma) (ABON)		
Version: AC		Page 17 of 26

Federal and official regulations.

## Section 9 Physical and chemical properties

### 9.1 Information on basic physical and chemical properties:

Appearance:	Liquid
Colour:	Colorless
Odour:	Odorless
Odour threshold:	Not available
pH:	Not available
Melting point/range (°C):	Not available
Boiling point/range (°C):	Not available
Flash point (°C):	Not available
Evaporation rate:	Not available
Flammability limit - lower (%):	Not available
Flammability (solid, gas):	Not available
Ignition temperature (°C):	Not available
Upper/lower flammability/explosive limits:	Not available
Vapour pressure (20°C):	Not available
Vapour density:	Not available
Relative Density:	Not available
Bulk density (kg/m <sup>3</sup> ):	Not available
Water solubility (g/l):	Not available
n-Octanol/Water (log Po/w):	Not available
Auto-ignition temperature:	Not available
Decomposition temperature:	Not available
Viscosity, dynamic (mPa.s):	Not available
Explosive properties:	Not available
Oxidising properties:	Not available
Molecular Formula:	Not available
Molecular Weight:	Not available

### 9.2. Other information:

Fat solubility(solvent– oil to be specified)	Not available
etc:	
Surface tension:	Not available
Dissociation constant in water( pKa):	Not available
Oxidation-reduction Potential:	Not available
Specific gravity:	Not available

## Section 10 Stability and reactivity

10.1 Reactivity:	The substance is stable under normal storage and handling conditions.
10.2 Chemical stability:	Stable at 2 to 30°C in closed containers under normal storage and

艾博生物医药 ABON Bio	质量体系技术规范 Quality System Technical Specification	艾博文件编号: MS-0218
		Agile 文件编号: MS-0218
文件名称 Document Name: Safety Data Sheet MONO Rapid Test Device (Whole Blood/ Serum/ Plasma) (ABON)		
Version: AC		Page 18 of 26

	handling conditions.
<b>10.3 Possibility of hazardous reactions:</b>	No dangerous reactions known.
<b>10.4 Conditions to avoid:</b>	Incompatible materials.
<b>10.5 Incompatible materials:</b>	Strong oxidizing agents, strong acids.
<b>10.6 Hazardous decomposition products:</b>	Carbon monoxide, carbon dioxide.

## Section 11 Toxicological information

### 11.1 Toxicokinetics, metabolism and distribution:

Non-human toxicological data: Not available

### 11.2 Information on toxicological effects:

#### Acute toxicity:

LD50(Oral, Rat): Not available

LD50(Dermal, Rabbit): Not available

LC50(Inhalation, Rat): Not available

Skin corrosion/Irritation: Not classified

Serious eye damage/irritation: Not classified

Respiratory or skin sensitization: Not classified

Germ cell mutagenicity: Not classified

Carcinogenicity: Not classified

Reproductive toxicity: Not classified

STOT- single exposure: Not classified

STOT-repeated exposure: Not classified

## Section 12 Ecological information

### Toxicity:

Acute toxicity		Time	Species	Method	Evaluation	Remarks
LC50	N/A	96h	Fish	OECD 203	N/A	N/A
EC50	N/A	48h	Daphnia	OECD 202	N/A	N/A
EC50	N/A	72h	Algae	OECD 201	N/A	N/A

Persistence and degradability: Not available.

Bioaccumulative potential: Not available.

Mobility in soil: Not available.

Results of PBT&vPvB assessment: Not available.

Other adverse effects: Not available.

## Section 13 Disposal considerations

**13.1 Waste treatment methods:** The material should be disposed of by incineration in a chemical incinerator in compliance with national and regional requirements.

**13.2 Product / Packaging disposal:** If empty container retains product residues, all label precautions must be observed. Dispose according to national or local regulations.

艾博生物医药 ABON Bio	质量体系技术规范 Quality System Technical Specification	艾博文件编号: MS-0218
		Agile 文件编号: MS-0218
文件名称 Document Name: Safety Data Sheet MONO Rapid Test Device (Whole Blood/ Serum/ Plasma) (ABON)		
Version: AC		Page 19 of 26

Section 14 Transport information			
	Land transport(ADR/RID)	Sea transport (IMDG)	Air transport (ICAO/IATA)
UN-Number	Not regulated	Not regulated	Not regulated
UN Proper shipping name	Not regulated	Not regulated	Not regulated
Transport hazard Class	Not regulated	Not regulated	Not regulated
Packaging group	Not regulated	Not regulated	Not regulated
Environmental hazards	No	No	No
Special precautions for user	See section 2.2	See section 2.2	See section 2.2
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not regulated	Not regulated	Not regulated

#### Section 15 Regulation information

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

Relevant information regarding authorization:	Not applicable.
Relevant information regarding restriction:	Not applicable.
Other EU regulations:	In Vitro diagnostics medical devices directive 98/79/EC.
Other National regulations:	Not applicable
Chemical Safety Assessment has been carried out?	YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>

#### Section 16 Other information

##### 16.1 Indication of changes:

Version 1.0 Amended by EU No 453/2010

##### 16.2 Relevant R- phrases (number and full text):

Not applicable.

##### 16.3 Training instructions:

Not applicable.

##### 16.4 Further information:

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.

##### 16.5 Notice to reader:

Employers should use this information only as a supplement to other information gathered by them, and should make independent judgment of suitability of this information to ensure proper use and protect the health and safety of employees. This information is furnished without warranty, and any use of the product not in conformance with this Safety Data Sheet, or in combination with any other product or process, is the responsibility of the user.

艾博生物医药 ABON Bio	质量体系技术规范 Quality System Technical Specification	艾博文件编号: MS-0218
		Agile 文件编号: MS-0218
文件名称 Document Name: Safety Data Sheet MONO Rapid Test Device (Whole Blood/ Serum/ Plasma) (ABON)		
Version: AC		Page 20 of 26

## Section 1 Identification of the substance/mixture and of the company/undertaking

### 1.1 Product identifier:

Identification on the label/Trade name: **Positive control of MONO Rapid Test Device (Whole Blood/Serum/Plasma)**

Additional identification: **Reference No.: IMO-402**

Identification of the product: See section 3

Index Number: Not available

REACH registration No.: Not available

### 1.2 Relevant identified uses of the substance and uses advised against:

#### 1.2.1 Identified uses:

In vitro diagnostic reagent. For professional use only.

#### 1.2.2 Uses advised against:

Not available.

### 1.3 Details of the supplier of the safety data sheet:

Supplier(Manufacturer): Abon Biopharm (Hangzhou) Co., Ltd  
 Address: #198 12<sup>th</sup> Street East, Hangzhou Economic & Technological Development Area, Hangzhou, 310018, P.R.China  
 Contact person(E-mail): abon.intelra@alere.com  
 Telephone: + 86-571-81638052  
 Fax: + 86-571-81638001

### 1.4 Emergency telephone Number:

+86-571-81638052

Available outside office hours? YES  NO

## Section 2 Hazards Identification

### 2.1 Classification of the substance/mixture:

#### 2.1.1 Classification:

The mixture is classified as following according to 1999/45/EC and REGULATION (EC) No 1272/2008:

REGULATION (EC) No 1272/2008	
Hazard classes/Hazard categories	Hazard codes
N/A	N/A

For full text of H- phrases: see section 2.2.

1999/45/EC	
Hazards characteristics	R-Phrases
N/A	N/A

For full text of R- phrases: see section 16.

### 2.2 label elements:

Hazard Pictograms: No hazard pictogram is used.

艾博生物医药 ABON Bio	质量体系技术规范 Quality System Technical Specification	艾博文件编号: MS-0218
		Agile 文件编号: MS-0218
文件名称 Document Name: Safety Data Sheet MONO Rapid Test Device (Whole Blood/ Serum/ Plasma) (ABON)		
Version: AC		Page 21 of 26

**Signal Word(S):** No signal word is used.

**Hazard Statement:** Not applicable.

**Precautionary statement:** Not applicable.

### 2.3 Other hazards:

Not available.

## Section 3 Composition/information on ingredients

**Substance/Mixture:** Mixture

**Ingredient(s):**

Chemical Name	Registration No.	CAS No.	EC No.	Concentration	Classification
Sodium Azide	-	26628-22-8	247-852-1	0.09%	H300 H400 H410

## Section 4 First aid measures

### 4.1 Description of first aid measures:

In all cases of doubt, or when symptoms persist, seek medical attention.

#### 4.1.1 In case of inhalation:

If inhalation, remove victim to fresh air and keep at rest in a position comfortable for breathing. If you feel unwell, seek medical attention.

#### 4.1.2 In case of skin contact:

Wash thoroughly with soap and water. Get medical attention in the unlikely event that irritation persists.

#### 4.1.3 In case of eyes contact:

Flush with running water for at least 15 minutes. If irritation persists get medical attention.

#### 4.1.4 In case of ingestion:

Rinse mouth with water. Obtain medical attention if symptoms occur.

### 4.2 Most important symptoms and effects, both acute and delayed:

The product is not classified as harmful to human health effect.

### 4.3 Indication of any immediate medical attention and special treatment needed:

If skin irritation or rash occurs, get medical advice/attention.

## Section 5 Fire-Fighting measures

### 5.1 Extinguishing media:

**Suitable extinguishing media:** Use extinguishing agents appropriate for surrounding fire.

**Unsuitable extinguishing media:** Not available.

### 5.2 Special hazards arising from the substance or mixture

In case of fire, the following can be released: carbon monoxide, carbon dioxide.

### 5.3 Special fire fighting methods and special protective actions for fire-fighters:

Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

## Section 6 Accidental release measures

艾博生物医药 ABON Bio	质量体系技术规范 Quality System Technical Specification	艾博文件编号: MS-0218
		Agile 文件编号: MS-0218
文件名称 Document Name: Safety Data Sheet MONO Rapid Test Device (Whole Blood/ Serum/ Plasma) (ABON)		
Version: AC		Page 22 of 26

#### 6.1 Personal precautions, protective equipment and emergency procedures:

- 6.1.1 For non-emergency personnel:** Provide adequate ventilation. Avoid inhalation of vapours. Avoid skin and eye contact. Refer to section 8 of SDS for personal protection details.
- 6.1.2 For emergency responders:** Wear an appropriate NIOSH/MSHA approved respirator if vapour is generated.
- 6.2 Environmental Precautions:** Do not allow material to be released to the environment without proper governmental permits.
- 6.3 Methods for Containment and Cleaning up:** Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Ensure adequate ventilation.
- 6.4 Reference to other sections:** See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for information on disposal.
- 6.5 Additional information:** Not applicable.

### Section 7 Handling and storage

#### 7.1 Precautions for safe handling:

- 7.1.1 Protective measures:** Good hygienic practices should be observed. Avoid contact with skin and eyes. Avoid breathing vapours. Work clothes should be washed separately at the end of each work day. Keep away from sources of ignition. Ensure good ventilation/exhaustion at the workplace.
- 7.1.2 Advice on general occupational hygiene:** Do not eat, drink and smoke in work areas. Wash hands after use. Remove contaminated clothing and protective equipment before entering eating areas.

#### 7.2 Conditions for safe storage, including any incompatibilities:

Material should be stored in a clean, dry environment at 2 to 30°C in original packaging and not exposed to ignition sources.

#### 7.3 Specific end use(s):

Use as per instructions for use.

### Section 8 Exposure Controls/Personal Protection

#### 8.1 Control parameters:

- 8.1.1 Occupational exposure limits:** Not available.
- 8.1.2 Additional exposure limits under the conditions of use:** Not available.
- 8.1.3 DNEL/DMEL and PNEC-Values:** Not available.

#### 8.2 Exposure controls:

- 8.2.1 Appropriate engineering controls:** Use adequate ventilation to keep airborne concentrations low.
- 8.2.2 Individual protection measures, such as personal protective equipment:**
- Eye/face protection:** No special protective equipment required.
- Hand protection:** No special protective equipment required.
- Body protection:** No special protective equipment required.
- Respiratory protection:** No special protective equipment required.
- Thermal hazards:** No special protective equipment required.
- 8.2.3 Environmental exposure controls:** Avoid discharge into the environment. According to local regulations, Federal and official regulations.

艾博生物医药 ABON Bio	质量体系技术规范 Quality System Technical Specification	艾博文件编号: MS-0218
		Agile 文件编号: MS-0218
文件名称 Document Name: Safety Data Sheet MONO Rapid Test Device (Whole Blood/ Serum/ Plasma) (ABON)		
Version: AC		Page 23 of 26

## Section 9 Physical and chemical properties

### 9.1 Information on basic physical and chemical properties:

Appearance:	Liquid
Colour:	Colorless
Odour:	Odorless
Odour threshold:	Not available
pH:	Not available
Melting point/range (°C):	Not available
Boiling point/range (°C):	Not available
Flash point (°C):	Not available
Evaporation rate:	Not available
Flammability limit - lower (%):	Not available
Flammability (solid, gas):	Not available
Ignition temperature (°C):	Not available
Upper/lower flammability/explosive limits:	Not available
Vapour pressure (20°C):	Not available
Vapour density:	Not available
Relative Density:	Not available
Bulk density (kg/m <sup>3</sup> ):	Not available
Water solubility (g/l):	Not available
n-Octanol/Water (log Po/w):	Not available
Auto-ignition temperature:	Not available
Decomposition temperature:	Not available
Viscosity, dynamic (mPa.s):	Not available
Explosive properties:	Not available
Oxidising properties:	Not available
Molecular Formula:	Not available
Molecular Weight:	Not available

### 9.2. Other information:

Fat solubility(solvent– oil to be specified)	Not available
etc:	
Surface tension:	Not available
Dissociation constant in water( pKa):	Not available
Oxidation-reduction Potential:	Not available
Specific gravity:	Not available

## Section 10 Stability and reactivity

10.1 Reactivity:	The substance is stable under normal storage and handling conditions.
10.2 Chemical stability:	Stable at 2 to 30°C in closed containers under normal storage and handling conditions.
10.3 Possibility of hazardous reactions:	No dangerous reactions known.

艾博生物医药 ABON Bio	质量体系技术规范 Quality System Technical Specification	艾博文件编号: MS-0218
		Agile 文件编号: MS-0218
文件名称 Document Name: Safety Data Sheet MONO Rapid Test Device (Whole Blood/ Serum/ Plasma) (ABON)		
Version: AC		Page 24 of 26

- 10.4 Conditions to avoid:** Incompatible materials.
- 10.5 Incompatible materials:** Strong oxidizing agents, strong acids.
- 10.6 Hazardous decomposition products:** Carbon monoxide, carbon dioxide.

## Section 11 Toxicological information

### 11.1 Toxicokinetics, metabolism and distribution:

**Non-human toxicological data:** Not available

### 11.2 Information on toxicological effects:

#### Acute toxicity:

**LD50(Oral, Rat):** Not available

**LD50(Dermal, Rabbit):** Not available

**LC50(Inhalation, Rat):** Not available

**Skin corrosion/Irritation:** Not classified

**Serious eye damage/irritation:** Not classified

**Respiratory or skin sensitization:** Not classified

**Germ cell mutagenicity:** Not classified

**Carcinogenicity:** Not classified

**Reproductive toxicity:** Not classified

**STOT- single exposure:** Not classified

**STOT-repeated exposure:** Not classified

## Section 12 Ecological information

### Toxicity:

Acute toxicity		Time	Species	Method	Evaluation	Remarks
LC50	N/A	96h	Fish	OECD 203	N/A	N/A
EC50	N/A	48h	Daphnia	OECD 202	N/A	N/A
EC50	N/A	72h	Algae	OECD 201	N/A	N/A

**Persistence and degradability:** Not available.

**Bioaccumulative potential:** Not available.

**Mobility in soil:** Not available.

**Results of PBT&vPvB assessment:** Not available.

**Other adverse effects:** Not available.

## Section 13 Disposal considerations

**13.1 Waste treatment methods:** The material should be disposed of by incineration in a chemical incinerator in compliance with national and regional requirements.

**13.2 Product / Packaging disposal:** If empty container retains product residues, all label precautions must be observed. Dispose according to national or local regulations.

## Section 14 Transport information



艾博生物医药 ABON Bio	质量体系技术规范 Quality System Technical Specification	艾博文件编号: MS-0218
		Agile 文件编号: MS-0218
文件名称 Document Name: Safety Data Sheet MONO Rapid Test Device (Whole Blood/ Serum/ Plasma) (ABON)		
Version: AC		Page 25 of 26

	Land transport(ADR/RID)	Sea transport (IMDG)	Air transport (ICAO/IATA)
UN-Number	Not regulated	Not regulated	Not regulated
UN Proper shipping name	Not regulated	Not regulated	Not regulated
Transport hazard Class	Not regulated	Not regulated	Not regulated
Packaging group	Not regulated	Not regulated	Not regulated
Environmental hazards	No	No	No
Special precautions for user	See section 2.2	See section 2.2	See section 2.2
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not regulated	Not regulated	Not regulated

### Section 15 Regulation information

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

Relevant information regarding authorization:	Not applicable.
Relevant information regarding restriction:	Not applicable.
Other EU regulations:	In Vitro diagnostics medical devices directive 98/79/EC.
Other National regulations:	Not applicable
Chemical Safety Assessment has been carried out?	YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>

### Section 16 Other information

#### 16.1 Indication of changes:

Version 1.0 Amended by EU No 453/2010

#### 16.2 Relevant R- phrases (number and full text):

Not applicable.

#### 16.3 Training instructions:

Not applicable.

#### 16.4 Further information:

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.

#### 16.5 Notice to reader:

Employers should use this information only as a supplement to other information gathered by them, and should make independent judgment of suitability of this information to ensure proper use and protect the health and safety of employees. This information is furnished without warranty, and any use of the product not in conformance with this Safety Data Sheet, or in combination with any other product or process, is the responsibility of the user.

艾博生物医药 ABON Bio	质量体系技术规范 Quality System Technical Specification	艾博文件编号: MS-0218
		Agile 文件编号: MS-0218
文件名称 Document Name: Safety Data Sheet MONO Rapid Test Device (Whole Blood/ Serum/ Plasma) (ABON)		
Version: AC		Page 26 of 26

## 文件更改概要

## Document Change Summary

审批单 编号 CO/DAF	更改概述 Summary of Changes
CO-10025804	仅更改页眉格式