

**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1. Product identifier**

<b>Name of the substance</b>	D-Dimer Calibrator & D-Dimer Plasma Control High & Low
<b>Identification number</b>	-
<b>Registration number</b>	-
<b>Synonyms</b>	None.
<b>Product code</b>	602
<b>Issue date</b>	01-December-2017
<b>Version number</b>	02
<b>Revision date</b>	02-August-2017
<b>Supersedes date</b>	28-May-2015

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

<b>Identified uses</b>	The IMUCLONE® D-Dimer ELISA allows for the quantitative measurement of D-dimer, cross-linked fibrin degradation product (XL-FDP), in human plasma.
<b>Uses advised against</b>	Use in accordance with supplier's recommendations.

**1.3. Details of the supplier of the safety data sheet**

**Corporate Headquarters** BioMedica Diagnostics Inc.  
94 Wentworth Road, PO Box 1030  
Windsor, Nova Scotia CANADA B0N 2T0

**Contact person** Corporate Phone: 1-902-798-5105  
Corporate Fax: 1-902-798-1025  
Email: info@biomedicadiagnostics.com  
Website: www.biomedicadiagnostics.com

**1.4. Emergency telephone number** US, Canada, Puerto Rico & Virgin Islands 1-800-255-3924  
International +1-813-248-0585  
Australia 1-300-954-583  
Brazil 0-800-591-6042  
China 400-120-0751  
India 000-800-100-4086  
Mexico 01-800-099-0731

**Contract number** MIS9591327

**SECTION 2: Hazards identification****2.1. Classification of the substance or mixture**

The substance has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

**Classification according to Directive 67/548/EEC or 1999/45/EC as amended**

This substance does not meet the criteria for classification according to Directive 67/548/EEC as amended.

**Classification according to Regulation (EC) No 1272/2008 as amended**

This substance does not meet the criteria for classification according to Regulation (EC) 1272/2008 as amended.

**Hazard summary**

<b>Physical hazards</b>	Not classified for physical hazards.
<b>Health hazards</b>	Not classified for health hazards.
<b>Environmental hazards</b>	Not classified for hazards to the environment.
<b>Specific hazards</b>	Dust may cause eye, skin and respiratory tract irritation.
<b>Main symptoms</b>	Mechanical irritation of skin, eyes and respiratory system.

**2.2. Label elements****Label according to Regulation (EC) No. 1272/2008 as amended**

<b>Contains:</b>	Human plasma
<b>Hazard pictograms</b>	None.
<b>Signal word</b>	None.

<b>Hazard statements</b>	None.
<b>Precautionary statements</b>	
<b>Prevention</b>	Observe good laboratory hygiene practices.
<b>Response</b>	Wash with plenty of water.
<b>Storage</b>	Store away from incompatible materials.
<b>Disposal</b>	Dispose of waste and residues in accordance with local authority requirements.
<b>Supplemental label information</b>	None.
<b>2.3. Other hazards</b>	Not a PBT or vPvB substance or mixture.

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

#### General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
Human plasma	100	N/A	-	-	
<b>Classification:</b>	<b>DSD:</b> -				
	<b>CLP:</b> -				

#### List of abbreviations and symbols that may be used above

CLP: Regulation No. 1272/2008.

DSD: Directive 67/548/EEC.

**Composition comments** All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume. The full text for all R- and H-phrases is displayed in section 16.

## SECTION 4: First aid measures

**General information** Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

### 4.1. Description of first aid measures

<b>Inhalation</b>	Move to fresh air. If breathing is difficult, give oxygen. Get medical attention if any discomfort continues.
<b>Skin contact</b>	For skin contact flush with large amounts of water while removing contaminated clothing. Get medical attention if irritation develops and persists.
<b>Eye contact</b>	In case of contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.
<b>Ingestion</b>	Rinse mouth thoroughly if dust is ingested. Get medical advice/attention if you feel unwell.

**4.2. Most important symptoms and effects, both acute and delayed** Dust may cause eye, skin and respiratory tract irritation.

**4.3. Indication of any immediate medical attention and special treatment needed** Provide general supportive measures and treat symptomatically.

## SECTION 5: Firefighting measures

**General fire hazards** Will burn if involved in a fire.

### 5.1. Extinguishing media

<b>Suitable extinguishing media</b>	Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the surrounding fire.
<b>Unsuitable extinguishing media</b>	None known.

**5.2. Special hazards arising from the substance or mixture** Fire will generate toxic and irritating gases.

### 5.3. Advice for firefighters

<b>Special protective equipment for firefighters</b>	Selection of respiratory protection for firefighting: follow the general fire precautions indicated in the workplace. Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Special fire fighting procedures</b>	Use standard firefighting procedures and consider the hazards of other involved materials.

## SECTION 6: Accidental release measures

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

- For non-emergency personnel** No special precautions are necessary beyond normal good hygiene practices. See Section 8 of the SDS for additional personal protection advice when handling this product.
- For emergency responders** Use personal protection recommended in Section 8 of the SDS.

**6.2. Environmental precautions** Avoid discharge into drains, water courses or onto the ground.

**6.3. Methods and material for containment and cleaning up** Avoid dust formation. Sweep or scoop up and remove.

**6.4. Reference to other sections** For personal protection, see Section 8 of the SDS. For waste disposal, see Section 13 of the SDS.

## SECTION 7: Handling and storage

**7.1. Precautions for safe handling** Avoid prolonged exposure. Avoid contact with skin and eyes. The source material for this product is of human origin and has been found to be non-reactive for Hepatitis B Surface Antigen (HBsAg), Hepatitis C Virus (HCV) and Human Immunodeficiency Virus Type 1 and Type 2 (HIV-1, HIV-2) using registered methods. As no known test method can provide complete assurance that products derived from human specimens will not transmit HBsAg, HCV, HIV-1, HIV-2 or other blood-borne pathogens, this reagent should be handled as recommended for any potentially infectious human specimen. Observe good laboratory hygiene practices.

**7.2. Conditions for safe storage, including any incompatibilities** Store at 2 - 8°C. Store in a closed container away from incompatible materials.

**7.3. Specific end use(s)** The IMUBIND® ADAMTS13 Autoantibody ELISA is intended for the measurement of ADAMTS13 IgG autoantibodies in human plasma.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

- Occupational exposure limits** No exposure limits noted for ingredient(s).
- Biological limit values** No biological exposure limits noted for the ingredient(s).
- Recommended monitoring procedures** Follow standard monitoring procedures.
- Derived no-effect level (DNEL)** Not available.
- Predicted no effect concentrations (PNECs)** Not available.

### 8.2. Exposure controls

**Appropriate engineering controls** No special ventilation requirements.

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

**General information** Personal protective equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.

**Eye/face protection** Wear dust-resistant safety goggles.

#### Skin protection

**- Hand protection** It is a good industrial hygiene practice to minimise skin contact. Chemical resistant gloves are recommended.

**- Other** It is a good industrial hygiene practice to minimise skin contact.

**Respiratory protection** In case of inadequate ventilation or risk of inhalation of dust, use suitable respiratory equipment with particle filter.

**Thermal hazards** Wear appropriate thermal protective clothing, when necessary.

**Hygiene measures** Handle in accordance with good industrial hygiene and safety practices.

**Environmental exposure controls** Inform appropriate managerial or supervisory personnel of all environmental releases.

## SECTION 9: Physical and chemical properties

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

**Appearance** Straw colored powder.

**Physical state** Solid.

**Form** Powder.

**Colour** Straw colored.

**Odour** None.

**Odour threshold** Not applicable.

<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not relevant.
<b>Flash point</b>	Not relevant.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Non flammable.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Vapour pressure</b>	Not relevant.
<b>Vapour density</b>	Not relevant.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	Soluble in water.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not relevant.
<b>Explosive properties</b>	Not relevant.
<b>Oxidizing properties</b>	Not oxidizing.
<b>9.2. Other information</b>	
<b>Percent volatile</b>	Not relevant.

## SECTION 10: Stability and reactivity

<b>10.1. Reactivity</b>	Stable at normal conditions.
<b>10.2. Chemical stability</b>	Material is stable under normal conditions.
<b>10.3. Possibility of hazardous reactions</b>	Polymerization will not occur.
<b>10.4. Conditions to avoid</b>	Keep away from heat.
<b>10.5. Incompatible materials</b>	Strong oxidising agents. Strong reducing agents. Strong acids.
<b>10.6. Hazardous decomposition products</b>	Carbon oxides. Nitrogen oxides.

## SECTION 11: Toxicological information

### Information on likely routes of exposure

<b>Inhalation</b>	Dust may irritate respiratory system.
<b>Skin contact</b>	Dust may irritate skin.
<b>Eye contact</b>	Dust in the eyes will cause irritation.
<b>Ingestion</b>	May cause discomfort if swallowed.
<b>Symptoms</b>	Mechanical irritation of skin, eyes and respiratory system.

### 11.1. Information on toxicological effects

<b>Acute toxicity</b>	May cause discomfort if swallowed.
<b>Skin corrosion/irritation</b>	Dust may irritate skin.
<b>Serious eye damage/eye irritation</b>	Dust may irritate the eyes.
<b>Respiratory sensitisation</b>	Not classified.
<b>Skin sensitisation</b>	Not classified.
<b>Germ cell mutagenicity</b>	Not classified.
<b>Carcinogenicity</b>	Not classified.
<b>Reproductive toxicity</b>	Not classified.
<b>Specific target organ toxicity - single exposure</b>	Not classified.

<b>Specific target organ toxicity - repeated exposure</b>	Not classified.
<b>Aspiration hazard</b>	Not classified.
<b>Mixture versus substance information</b>	Not available.
<b>Other information</b>	No other specific acute or chronic health impact noted.

## SECTION 12: Ecological information

<b>12.1. Toxicity</b>	No toxicity data noted for the ingredient(s).
<b>12.2. Persistence and degradability</b>	No data available.
<b>12.3. Bioaccumulative potential</b>	No data available.
<b>Partition coefficient n-octanol/water (log Kow)</b>	Not available.
<b>Bioconcentration factor (BCF)</b>	Not available.
<b>12.4. Mobility in soil</b>	Not available.
<b>Mobility in general</b>	The product is soluble in water.
<b>12.5. Results of PBT and vPvB assessment</b>	Not a PBT or vPvB substance or mixture.
<b>12.6. Other adverse effects</b>	No data available.

## SECTION 13: Disposal considerations

<b>13.1. Waste treatment methods</b>	
<b>Residual waste</b>	Dispose in accordance with all applicable regulations.
<b>Contaminated packaging</b>	Empty containers should be taken to an approved waste handling site for recycling or disposal.
<b>EU waste code</b>	The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.
<b>Disposal methods/information</b>	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Contaminated instruments and surfaces should be disinfected in accordance with your employer's chemical-specific and universal/standard precautions.

## SECTION 14: Transport information

### ADR

Not regulated as dangerous goods.

### RID

Not regulated as dangerous goods.

### ADN

Not regulated as dangerous goods.

### IATA

Not regulated as dangerous goods.

### IMDG

Not regulated as dangerous goods.

<b>14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>	Not applicable.
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## SECTION 15: Regulatory information

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

#### EU regulations

**Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I and II, as amended**

Not listed.

**Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended**

Not listed.

**Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended**

Not listed.

**Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended**

Not listed.

- Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended**  
Not listed.
- Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex V as amended**  
Not listed.
- Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry, as amended**  
Not listed.
- Regulation (EC) No. 1907/2006, REACH Article 59(10) Candidate List as currently published by ECHA**  
Not listed.

#### Authorisations

- Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended**  
Not listed.

#### Restrictions on use

- Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended**  
Not listed.
- Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work, as amended**  
Not listed.
- Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding, as amended**  
Not listed.

#### Other EU regulations

- Directive 2012/18/EU on major accident hazards involving dangerous substances**  
Not listed.
- Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work**  
Not listed.
- Directive 94/33/EC on the protection of young people at work**  
Not listed.

#### Other regulations

This product does not meet the criteria for classification according to Regulation (EC) 1272/2008 (CLP Regulation) and Directive 67/548/EEC and their amendments respectively. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006 as amended.

#### National regulations

Follow national regulation for work with chemical agents.

#### 15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out.

## SECTION 16: Other information

#### List of abbreviations

DSD: Directive 67/548/EEC.  
CLP: Regulation No. 1272/2008.  
DNEL: Derived No-Effect Level.  
PNEC: Predicted No-Effect Concentration.

#### References

Not available.

#### Information on evaluation method leading to the classification of mixture

The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.

#### Full text of any statements or R-phrases and H-statements under Sections 2 to 15

None.

#### Training information

Follow training instructions when handling this material.

#### Disclaimer

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