

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

<b>Trade name or designation of the mixture</b>	ACTICLOT® Activator Reagent
<b>Registration number</b>	-
<b>Synonyms</b>	None.
<b>Product code</b>	ACC-45 ACTICLOT® C
<b>Issue date</b>	01-December-2017
<b>Version number</b>	02
<b>Revision date</b>	27-July-2017
<b>Supersedes date</b>	22-June-2015

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

<b>Identified uses</b>	ACTICLOT® C is intended for the measurement of Protein C activity in human plasma via an end-point clotting assay.
<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 product has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

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

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

**Hazard summary** Avoid contact with eyes and skin. Do not ingest or inhale.

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

<b>Hazard pictograms</b>	None.
<b>Signal word</b>	None.
<b>Hazard statements</b>	The mixture does not meet the criteria for classification.

**Precautionary statements**

<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.

**Supplemental label information** None.

**2.3. Other hazards** Not a PBT or vPvB substance or mixture.

## SECTION 3: Composition/information on ingredients

### 3.2. Mixtures

The components are not hazardous or are below required disclosure limits.

## 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

**Inhalation** Move to fresh air. If breathing is difficult, give oxygen. Get medical attention if any discomfort continues.

**Skin contact** For skin contact flush with large amounts of water while removing contaminated clothing. Get medical attention if irritation develops and persists.

**Eye contact** 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.

**Ingestion** 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

**Suitable extinguishing media** Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the surrounding fire.

**Unsuitable extinguishing media** None known.

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

### 5.3. Advice for firefighters

**Special protective equipment for firefighters** 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.

**Special fire fighting procedures** 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. 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)** ACTICLOT® C is intended for the measurement of Protein C activity in human plasma via an end-point clotting assay.

## 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** White powder.

**Physical state** Solid.

**Form** Powder.

**Colour** White.

**Odour** None.

**Odour threshold** Not applicable.

**pH** Not available.

**Melting point/freezing point** Not available.

**Initial boiling point and boiling range** Not available.

**Flash point** Not available.

**Evaporation rate** Not available.

**Flammability (solid, gas)** Non flammable.

#### Upper/lower flammability or explosive limits

**Flammability limit - lower (%)** Not available.

**Flammability limit - upper (%)** Not available.

**Vapour pressure** Not available.

**Vapour density** Not available.

**Relative density** Not available.

**Solubility(ies)** Soluble in water.

**Partition coefficient (n-octanol/water)** Not available.

**Auto-ignition temperature** Not available.

**Decomposition temperature** Not available.

**Viscosity** Not available.

**Explosive properties** Not relevant.

**Oxidizing properties** Not oxidising.

### 9.2. Other information

**Percent volatile** Not available.

## SECTION 10: Stability and reactivity

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

## SECTION 11: Toxicological information

### Information on likely routes of exposure

Inhalation	Dust may irritate respiratory system.
Skin contact	Dust may irritate skin.
Eye contact	Dust in the eyes will cause irritation.
Ingestion	May cause discomfort if swallowed.

**Symptoms** Mechanical irritation of skin, eyes and respiratory system.

### 11.1. Information on toxicological effects

Acute toxicity	May cause discomfort if swallowed.
Skin corrosion/irritation	Dust may irritate skin.
Serious eye damage/eye irritation	Dust may irritate the eyes.
Respiratory sensitisation	Not classified.
Skin sensitisation	Not classified.
Germ cell mutagenicity	Not classified.
Carcinogenicity	Not classified.
Reproductive toxicity	Not classified.
Specific target organ toxicity - single exposure	Not classified.
Specific target organ toxicity - repeated exposure	Not classified.
Aspiration hazard	Not classified.
Mixture versus substance information	Not available.
Other information	No other specific acute or chronic health impact noted.

## SECTION 12: Ecological information

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

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Residual waste	Dispose in accordance with all applicable regulations.
Contaminated packaging	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>	This preparation contains a small amount of sodium azide which can react with copper, lead, brass or solder in plumbing systems and form potentially explosive metal azides. If preparation enters drain, flush with a large volume of water to prevent azide build-up.

## 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.

**14.7. Transport in bulk according to Annex II of MARPOL 73/78 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

**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.

<b>Other regulations</b>	This mixture does not meet the criteria for classification according to Regulation (EC) 1272/2008 as amended. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006 as amended.
<b>National regulations</b>	Follow national regulation for work with chemical agents.
<b>15.2. Chemical safety assessment</b>	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 H-statements not written out in full under Sections 2 to 15

None.

### Training information

Follow training instructions when handling this material.

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