

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

1.1. Product identifier

Trade name or designation of the mixture	Dilution Buffer
Registration number	-
Synonyms	None.
Product code	ACC-45 ACTICLOT® C
Issue date	01-December-2017
Version number	02
Revision date	27-July-2017
Supersedes date	21-June-2015

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

Identified uses	ACTICLOT® C is intended for the measurement of Protein C activity in human plasma via an end-point clotting assay.
Uses advised against	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 mixture 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

Health hazards

Skin corrosion/irritation	Category 2	H315 - Causes skin irritation.
Serious eye damage/eye irritation	Category 2	H319 - Causes serious eye irritation.
Reproductive toxicity	Category 1B	H360 - May damage fertility or the unborn child.

Hazard summary Causes skin and eye irritation. May damage fertility or the unborn child.

2.2. Label elements

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

Contains: Imidazole

Hazard pictograms



Signal word Danger

Hazard statements

H315	Causes skin irritation.
H319	Causes serious eye irritation.
H360	May damage fertility or the unborn child.

Precautionary statements

Prevention

P280	Wear protective gloves/protective clothing/eye protection/face protection.
P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.

Response

P302 + P352	IF ON SKIN: Wash with plenty of water.
P332 + P313	If skin irritation occurs: Get medical advice/attention.
P362	Take off contaminated clothing and wash before reuse.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337 + P313	If eye irritation persists: Get medical advice/attention.
P308 + P313	IF exposed or concerned: Get medical advice/attention.

Storage

P405	Store locked up.
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Disposal

P501	Dispose of contents/container in accordance with local/regional/national/international regulations.
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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

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
Sodium chloride	5 - 8	7647-14-5 231-598-3	01-2119485491-33-XXXX	-	
Classification:	-				
Imidazole	1 - < 2	288-32-4 206-019-2	-	-	
Classification:	Acute Tox. 4;H302, Skin Corr. 1C;H314, Eye Dam. 1;H318, Repr. 1B;H360				

List of abbreviations and symbols that may be used above

#: This substance has been assigned Community workplace exposure limit(s).

Composition comments All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

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. For breathing difficulties, oxygen may be necessary. Call a physician if symptoms develop or persist.
Skin contact	Wash skin thoroughly with soap and water. 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 with water. Never give anything by mouth to an unconscious person. Get immediate medical attention.

4.2. Most important symptoms and effects, both acute and delayed Ingestion may cause irritation and malaise. Symptoms include itching, burning, redness and tearing.

4.3. Indication of any immediate medical attention and special treatment needed Treat symptomatically. Symptoms may be delayed.

SECTION 5: Firefighting measures

General fire hazards The product is not flammable.

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	When heated to decomposition, may produce hydrazoic acid fumes.
5.3. Advice for firefighters	
Special protective equipment for firefighters	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	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.
For emergency responders	Use personal protection as recommended in section 8 of the SDS.
6.2. Environmental precautions	Do not allow to enter drains, sewers or watercourses. This mixture 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. Follow proper disposal procedures.
6.3. Methods and material for containment and cleaning up	Absorb spill with vermiculite or other inert material. Dispose of waste in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.
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 contact with skin and eyes. Do not handle until all safety precautions have been read and understood. Wash thoroughly after handling. In case of insufficient ventilation, wear suitable respiratory equipment. Handle and open container with care.
7.2. Conditions for safe storage, including any incompatibilities	Store at 2-8°C (35-46°F). 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	Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.
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 approved safety glasses or goggles.
Skin protection	
- Hand protection	Wear appropriate chemical resistant gloves.
- Other	Wear lab coat or other protective garments. Remove contaminated clothing promptly.
Respiratory protection	In case of inadequate ventilation or risk of inhalation of vapours, use suitable respiratory equipment.
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	Clear, colourless liquid.
Physical state	Liquid.
Form	Liquid.
Colour	Colourless, clear.
Odour	None.
Odour threshold	Not available.
pH	7.4
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not applicable.
Flammability (solid, gas)	Not available.
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)	Water soluble.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Explosive properties	Not explosive.
Oxidizing properties	Not oxidising.
9.2. Other information	No relevant additional information available.

SECTION 10: Stability and reactivity

10.1. Reactivity	Contact with acids liberates very toxic gas.
10.2. Chemical stability	Material is stable under normal conditions.
10.3. Possibility of hazardous reactions	Hazardous polymerisation does not occur.
10.4. Conditions to avoid	Protect against direct sunlight.
10.5. Incompatible materials	Strong oxidising agents. Strong acids. Strong reducing agents.
10.6. Hazardous decomposition products	Nitrogen oxides, carbon monoxide and carbon dioxide. Thermal decomposition can lead to release of irritating gases and vapors, including hydrazoic acid vapor.

SECTION 11: Toxicological information

General information	Occupational exposure to the substance or mixture may cause adverse effects.
Information on likely routes of exposure	
Inhalation	Vapours may irritate throat and respiratory system and cause coughing.
Skin contact	Causes skin irritation.
Eye contact	Causes serious eye irritation.
Ingestion	Harmful if swallowed.
Symptoms	Ingestion may cause irritation and malaise. Symptoms include itching, burning, redness and tearing.
11.1. Information on toxicological effects	
Acute toxicity	Harmful if swallowed.

Components	Species	Test results
Imidazole (CAS 288-32-4)		
Acute		
<i>Oral</i>		
LD50	Rat	970 mg/kg
Skin corrosion/irritation	Causes skin irritation.	
Serious eye damage/eye irritation	Causes serious eye irritation.	
Respiratory sensitisation	Not classified.	
Skin sensitisation	Not a skin sensitiser.	
Germ cell mutagenicity	Not classified.	
Carcinogenicity	Not classifiable as to carcinogenicity to humans.	
Reproductive toxicity	May damage fertility or the unborn child.	
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 is available on the degradability of this product.
12.3. Bioaccumulative potential	Not 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	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods	
Residual waste	Dispose in accordance with all applicable regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal.
EU waste code	Waste codes should be assigned by the user based on the application for which the product was used.
Disposal methods/information	Dispose in accordance with all applicable regulations. 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.

Other regulations

This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006. The product is classified and labelled in accordance with Regulation (EC) 1272/2008 (CLP Regulation) as amended and respective national laws implementing EC directives. Young people under 18 years old are not allowed to work with this product according to the EU Directive 94/33/EC on the protection of young people at work.

National regulations

The product has been classified according to the legislation in force.

15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

List of abbreviations

DNEL: Derived No-Effect Level.

PNEC: Predicted No-Effect Concentration.

References

HSDB

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

H302 Harmful if swallowed.
H314 Causes severe skin burns and eye damage.
H318 Causes serious eye damage.
H360 May damage fertility or the unborn child.

Training information

Follow training instructions when handling this material.

Disclaimer

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