

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

1.1. Product identifier

Trade name or designation of the mixture	Imidazole Buffer, pH 7.2, 10X
Registration number	-
Synonyms	R1
Product code	101201
Issue date	01-December-2017
Version number	02
Revision date	18-October-2017
Supersedes date	14-July-2015

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

Identified uses	SPECTROLYSE® PAI-1 is intended for the quantitative determination of Plasminogen Activator Inhibitor Type-1 (PAI-1) activity in human plasma. For In Vitro Diagnostic use only.
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

Acute toxicity, oral	Category 4	H302 - Harmful if swallowed.
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.

Environmental hazards

Hazardous to the aquatic environment, long-term aquatic hazard	Category 3	H412 - Harmful to aquatic life with long lasting effects.
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Hazard summary Harmful if swallowed. 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, Sodium azide

Hazard pictograms



Signal word

Warning

Hazard statements

H302	Harmful if swallowed.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H360	May damage fertility or the unborn child.
H412	Harmful to aquatic life with long lasting effects.

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.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
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 EUH032 - Contact with acids liberates very toxic gas.

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
Imidazole	55 - 65	288-32-4 206-019-2	-	-	
Classification:	Acute Tox. 4;H302, Skin Corr. 1C;H314, Eye Dam. 1;H318, Repr. 1B;H360				
Ethylenediamine tetraacetic acid	25 - 30	60-00-4 200-449-4	-	607-429-00-8	
Classification:	Eye Irrit. 2;H319				
Sodium azide	1 < 2.0	26628-22-8 247-852-1	-	011-004-00-7	#
Classification:	Acute Tox. 2;H300, Aquatic Acute 1;H400, Aquatic Chronic 1;H410				

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. The full text for all H-statements 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

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) SPECTROLYSE® PAI-1 is intended for the quantitative determination of Plasminogen Activator Inhibitor Type-1 (PAI-1) activity in human plasma. For In Vitro Diagnostic use only.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value
Sodium azide (CAS 26628-22-8)	STEL	0.3 mg/m ³
	TWA	0.1 mg/m ³

EU. Indicative Exposure Limit Values in Directives 91/322/EEC, 2000/39/EC, 2006/15/EC, 2009/161/EU

Components	Type	Value
Sodium azide (CAS 26628-22-8)	STEL	0.3 mg/m ³
	TWA	0.1 mg/m ³

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.
Exposure guidelines	Follow standard monitoring procedures.
UK EH40 WEL: Skin designation	
Sodium azide (CAS 26628-22-8)	Can be absorbed through the skin.

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) Soluble.

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

Auto-ignition temperature Not available.

Decomposition temperature Not available.

Viscosity Not available.

Explosive properties Not available.

Oxidizing properties Not available.

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	Contact with acids liberates toxic gas.
10.4. Conditions to avoid	Protect against direct sunlight.
10.5. Incompatible materials	Strong oxidising agents.
10.6. Hazardous decomposition products	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. Sodium azide may be absorbed through the skin and result in systemic effects.
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
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Imidazole (CAS 288-32-4)

Acute

Oral

LD50

Rat

970 mg/kg

Sodium azide (CAS 26628-22-8)

Acute

Dermal

LD50

Rabbit

20 mg/kg

Oral

LD50

Rat

27 mg/kg

Skin corrosion/irritation Causes skin irritation.

Serious eye damage/eye irritation Causes 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 Suspected of damaging 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 Harmful to aquatic life with long lasting effects.

Components	Species	Test results
Sodium azide (CAS 26628-22-8)		
Aquatic		
Algae	EC50	Pseudokirchnerella subcapitata 0.35 mg/l, 96 hours
Fish	LC50	Fish 5.7 mg/l, 96 hours
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	No data available.	

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

Sodium azide (CAS 26628-22-8)

Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Ethylenediamine tetraacetic acid (CAS 60-00-4)

Sodium azide (CAS 26628-22-8)

Directive 94/33/EC on the protection of young people at work

Sodium azide (CAS 26628-22-8)

Other regulations

The product is classified and labelled in accordance with Regulation (EC) 1272/2008 (CLP Regulation) as amended and respective national laws implementing EC directives. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006. 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

H300 Fatal if swallowed.
H302 Harmful if swallowed.
H314 Causes severe skin burns and eye damage.
H318 Causes serious eye damage.
H319 Causes serious eye irritation.
H360 May damage fertility or the unborn child.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.

Training information

Follow training instructions when handling this material.

Disclaimer

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