SAFETY DATA SHEET

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

1.1. Product identifier

Trade name or designation of the mixture	DVVtest® 10, DVVtest® 25
Registration number	-
Synonyms	None.
Product code	810; 825
Issue date	01-December-2017
Version number	02
Revision date	14-July-2017
Supersedes date	10-July-2015

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

Identified uses	DVVtest® is a dilute Russell's Viper Venom Time (dRVVT) test intended for the determination of Lupus Anticoagulants (LA) in patient plasma.
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		
Serious eye damage/eye irritation	Category 2	H319 - Causes serious eye irritation.
Environmental hazards		
Hazardous to the aquatic environment, long-term aquatic hazard	Category 3	H412 - Harmful to aquatic life with long lasting effects.

Hazard summary Contact with acids liberates very toxic gas. Irritating to eyes. Dangerous for the environment if discharged into watercourses.

2.2. Label elements

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

Hazard pictograms

Signal word Warning

Hazard statements

H319	Causes serious eye irritation.
H412	Harmful to aquatic life with long lasting effects.

Precautionary statements

Prevention

P264	Wash thoroughly after handling.
P273	Avoid release to the environment.
P280	Wear eye protection/face protection.

Response

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.

Storage Not assigned.

Disposal

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

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
Calcium chloride, dihydrate	15 - 20	10035-04-8 -	-	-	
Classification: Eye Irrit. 2;H319					
Vinylpyrrolidinone polymer	1 - 5	9003-39-8 -	-	-	
Classification: -					
Sodium azide	0.1 - 1	26628-22-8 247-852-1	-	011-004-00-7	#
Classification: Acute Tox. 2;H300, Acute Tox. 1;H310, Aquatic Acute 1;H400, Aquatic Chronic 1;H410					

List of abbreviations and symbols that may be used above

DSD: Directive 67/548/EEC.
CLP: Regulation No. 1272/2008.
#: This substance has been assigned Community workplace exposure limit(s).

Composition comments The full text for all H-statements is displayed in section 16. 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 Severe eye irritation. 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 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. When heated to decomposition, may produce hydrazoic acid fumes.

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 Avoid dust formation. 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 Sweep up or vacuum up spillage and collect in suitable container for disposal. 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 inhalation of dust. Avoid contact with skin and eyes. Provide appropriate exhaust ventilation at places where dust is formed. Wash thoroughly after handling. Observe good industrial hygiene practices.

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) DVVtest® is a dilute Russell's Viper Venom Time (dRVVT) test intended for the determination of Lupus Anticoagulants (LA) in patient plasma.

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/m3
	TWA	0.1 mg/m3

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/m3
	TWA	0.1 mg/m3

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

UK EH40 WEL: Skin designation

Sodium azide (CAS 26628-22-8) Can be absorbed through the skin.

8.2. Exposure controls

Appropriate engineering controls	Observe occupational exposure limits and minimise the risk of inhalation of dust and fumes.

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	Remove contaminated clothing promptly.
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 available.
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)	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	The product is stable and non reactive under normal conditions of use, storage and transport.
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	Heat, flames and sparks.
10.5. Incompatible materials	Strong oxidising agents. Strong acids. Strong reducing agents.

10.6. Hazardous decomposition products Thermal decomposition can lead to release of irritating gases and vapors, including hydrazoic acid vapor. Carbon oxides. Nitrogen oxides.

SECTION 11: Toxicological information

General information Occupational exposure to the substance or mixture may cause adverse effects.

Information on likely routes of exposure

Inhalation Dust may irritate respiratory system.

Skin contact Dust may irritate skin.

Eye contact Causes serious eye irritation.

Ingestion May cause discomfort if swallowed.

Symptoms Ingestion may cause irritation and malaise. Symptoms include itching, burning, redness and tearing.

11.1. Information on toxicological effects

Components	Species	Test results
Calcium chloride, dihydrate (CAS 10035-04-8)		
Acute		
Oral		
LD50	Rat	> 1000 mg/kg
Sodium azide (CAS 26628-22-8)		
Acute		
Dermal		
LD50	Rabbit	20 mg/kg
Oral		
LD50	Rat	27 mg/kg

Skin corrosion/irritation Dust may irritate skin.

Serious eye damage/eye irritation Causes serious eye irritation.

Respiratory sensitisation Not classified.

Skin sensitisation Not classified.

Germ cell mutagenicity Not classified.

Carcinogenicity Not classifiable as to carcinogenicity to humans.

IARC Monographs. Overall Evaluation of Carcinogenicity

Vinylpyrrolidinone polymer (CAS 9003-39-8) 3 Not classifiable as to carcinogenicity to humans.

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 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	No data 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.
EU waste code	The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Disposal methods/information	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. 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.
General information	The transportation information provided represents the regulatory transport classification of the product without consideration to packaging, quantity, or modal restrictions and exceptions. It is the user's responsibility to determine the appropriate packaging and modal requirements and/or limitations for the product quantity being shipped. It may be eligible for Excepted Quantity exemption, dependant on quantity of units within the outer package.

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

Calcium chloride, dihydrate (CAS 10035-04-8)
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	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.
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.
LD50: Lethal Dose, 50%.

References

IARC Monographs. Overall Evaluation of Carcinogenicity
HSDB (2005)

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.
H310 Fatal in contact with skin.
H319 Causes serious eye irritation.
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.

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