

## 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>	DVVconfirm® 5 ; DVVconfirm® 10
<b>Registration number</b>	-
<b>Synonyms</b>	None.
<b>Product code</b>	815, 815L
<b>Issue date</b>	01-December-2017
<b>Version number</b>	02
<b>Revision date</b>	14-July-2017
<b>Supersedes date</b>	10-July-2015

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

<b>Identified uses</b>	DVVconfirm® is used to confirm the presence of LA in plasma which tested positive using DVVtest®.
<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 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 1	H318 - Causes serious eye damage.
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** Contact with acid liberates toxic gas. Causes serious eye damage. May damage fertility or the unborn child. Causes skin irritation. Dangerous for the environment if discharged into watercourses.

### 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.  
H318 Causes serious eye damage.  
H360 May damage fertility or the unborn child.  
H412 Harmful to aquatic life with long lasting effects.

## Precautionary statements

### Prevention

P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P264 Wash thoroughly after handling.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/protective clothing/eye protection/face protection.

### 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.  
P310 Immediately call a POISON CENTER/doctor.  
P332 + P313 If skin irritation occurs: Get medical advice/attention.  
P362 + P364 Take off contaminated clothing and wash it before reuse.  
P308 + P313 IF exposed or concerned: Get medical advice/attention.

### Storage

P405 Store locked up.

### 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

Contact with acids liberates toxic gas. 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	25 - 30	7647-14-5 231-598-3	01-2119485491-33-XXXX	-	
<b>Classification:</b>	-				
Calcium chloride, dihydrate	10 - 15	10035-04-8	-	-	
<b>Classification:</b>	Eye Irrit. 2;H319				
Imidazole	3 - <5	288-32-4 206-019-2	-	-	
<b>Classification:</b>	Acute Tox. 4;H302, Skin Corr. 1C;H314, Eye Dam. 1;H318, Repr. 1B;H360				
Vinylpyrrolidinone polymer	1 - 4	9003-39-8	-	-	
<b>Classification:</b>	-				
Sodium azide	0.1 - 1	26628-22-8 247-852-1	-	011-004-00-7	#
<b>Classification:</b>	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 R- and H-phrases 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. If breathing is difficult, give oxygen. Get medical attention if any discomfort occurs.

**Skin contact** Wash skin thoroughly with soap and water. Get medical attention if irritation develops and persists.

**Eye contact** Flush eyes thoroughly with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention immediately.

**Ingestion** Rinse mouth thoroughly if dust is ingested. Get medical attention if symptoms occur.

**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. Causes skin irritation.

**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)** DVVconfirm® is used to confirm the presence of LA in plasma which tested positive using DVVtest®.

## 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 <sup>3</sup>
	TWA	0.1 mg/m <sup>3</sup>

### 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 <sup>3</sup>
	TWA	0.1 mg/m <sup>3</sup>

**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. Wear protective gloves.

- **Other** Wear protective gloves. 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.

<b>Flammability limit - upper (%)</b>	Not available.
<b>Vapour pressure</b>	Not available.
<b>Vapour density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	Soluble.
<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 available.
<b>Explosive properties</b>	Not available.
<b>Oxidizing properties</b>	Not available.
<b>9.2. Other information</b>	No relevant additional information available.

## SECTION 10: Stability and reactivity

<b>10.1. Reactivity</b>	The product is stable and non reactive under normal conditions of use, storage and transport.
<b>10.2. Chemical stability</b>	Material is stable under normal conditions.
<b>10.3. Possibility of hazardous reactions</b>	Contact with acids liberates toxic gas.
<b>10.4. Conditions to avoid</b>	Heat, flames and sparks.
<b>10.5. Incompatible materials</b>	Strong oxidising agents. Strong acids. Strong reducing agents.
<b>10.6. Hazardous decomposition products</b>	Thermal decomposition can lead to release of irritating gases and vapors, including hydrazoic acid vapor. Carbon oxides. Nitrogen oxides.

## SECTION 11: Toxicological information

<b>General information</b>	Occupational exposure to the substance or mixture may cause adverse effects.
<b>Information on likely routes of exposure</b>	
<b>Inhalation</b>	Dust may irritate respiratory system.
<b>Skin contact</b>	Causes skin irritation.
<b>Eye contact</b>	Causes serious eye damage.
<b>Ingestion</b>	May cause discomfort if swallowed.
<b>Symptoms</b>	Ingestion may cause irritation and malaise. Symptoms include itching, burning, redness and tearing. Causes skin irritation.

### 11.1. Information on toxicological effects

**Acute toxicity** May cause discomfort if swallowed.

Components	Species	Test results
Calcium chloride, dihydrate (CAS 10035-04-8)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	> 1000 mg/kg
Imidazole (CAS 288-32-4)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	970 mg/kg
Sodium azide (CAS 26628-22-8)		
<b>Acute</b>		
<i>Dermal</i>		
LD50	Rabbit	20 mg/kg
<i>Oral</i>		
LD50	Rat	27 mg/kg
<b>Skin corrosion/irritation</b>	Causes skin irritation.	
<b>Serious eye damage/eye irritation</b>	Causes serious eye damage.	
<b>Respiratory sensitisation</b>	Not classified.	
<b>Skin sensitisation</b>	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** 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** Harmful to aquatic life with long lasting effects.

Components		Species	Test results
Sodium azide (CAS 26628-22-8)			
<b>Aquatic</b>			
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.

## 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. 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.

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.  
H302 Harmful if swallowed.  
H310 Fatal in contact with skin.  
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**

The information above is provided in good faith. It is believed to be accurate and represents the best information currently available to us. HOWEVER, WE MAKE NO WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OF ANY OTHER TYPE, EXPRESSED OR IMPLIED, WITH RESPECT TO PRODUCTS DESCRIBED OR DATA OR INFORMATION PROVIDED, AND WE ASSUME NO LIABILITY RESULTING FROM THE USE OF SUCH PRODUCTS, DATA OR INFORMATION. Users should make their own investigations to determine the suitability of the information for their particular purposes, and the user assumes all risk arising from their use of the material. The user is required to comply with all laws and regulations relating to the purchase, use, storage and disposal of the material, and must be familiar with and follow generally accepted safe handling procedures. In no event shall BioMedica Diagnostics be liable for any claims, losses, or damages of any individual or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if BioMedica Diagnostics has been advised of the possibility of such damages.