

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

1.1. Product identifier

Trade name or designation of the mixture	OPD substrate
Registration number	-
Synonyms	None.
Product code	822 OPD Substrate, Z-CHEM46
Issue date	01-December-2017
Version number	02
Revision date	17-July-2017
Supersedes date	22-June-2015

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

Identified uses	The IMUBIND Plasma PAI-1 ELISA is an enzyme-linked immunosorbent assay for the quantitative measurement of human Plasminogen Activator Inhibitor Type-1 (PAI-1) antigen in 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
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Contract number	MIS9591327
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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.
Serious eye damage/eye irritation	Category 2	H319 - Causes serious eye irritation.
Skin sensitisation	Category 1	H317 - May cause an allergic skin reaction.
Germ cell mutagenicity	Category 2	H341 - Suspected of causing genetic defects.
Carcinogenicity	Category 2	H351 - Suspected of causing cancer.

Environmental hazards

Hazardous to the aquatic environment, long-term aquatic hazard	Category 1	H410 - Very toxic to aquatic life with long lasting effects.
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Hazard summary	Harmful if swallowed. Causes serious eye irritation. May cause allergic skin reaction. Suspected of causing genetic defects. Suspected of causing cancer.
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2.2. Label elements

Label according to Regulation (EC) No. 1272/2008 as amended**Contains:** o-Phenylenediamine dihydrochloride**Hazard pictograms****Signal word** Warning**Hazard statements**

H302	Harmful if swallowed.
H319	Causes serious eye irritation.
H317	May cause an allergic skin reaction.
H341	Suspected of causing genetic defects.
H351	Suspected of causing cancer.
H410	Very toxic to aquatic life with long lasting effects.

Precautionary statements**Prevention**

P264	Wash thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
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.
P261	Avoid breathing dust.
P273	Avoid release to the environment.

Response

P301 + P312	IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
P330	Rinse mouth.
P308 + P313	IF exposed or concerned: Get medical advice/attention.
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.
P302 + P352	IF ON SKIN: Wash with plenty of soap and water.
P333 + P313	If skin irritation or rash occurs: Get medical advice/attention.
P362	Take off contaminated clothing and wash before reuse.
P391	Collect spillage.

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
o-Phenylenediamine dihydrochloride	25 - 30	615-28-1 210-418-7	-	612-146-00-8	
Classification:	Acute Tox. 3;H301, Acute Tox. 4;H312, Skin Sens. 1;H317, Eye Irrit. 2;H319, Acute Tox. 4;H332, Muta. 2;H341, Carc. 2;H351, Aquatic Acute 1;H400, Aquatic Chronic 1;H410				

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 injured person into fresh air and keep person calm under observation. If breathing is difficult, trained personnel should give oxygen. Get medical attention if any discomfort continues.

Skin contact

Take off immediately all contaminated clothing. Flush skin thoroughly with water. In case of eczema or other skin disorders: Seek medical attention and take along these instructions.

Eye contact	Dust in the eyes: Do not rub eyes. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove any contact lenses and open eyelids wide apart. Get medical attention if irritation persists after washing.
Ingestion	Rinse mouth thoroughly. Drink 1 or 2 glasses of water. Never give anything by mouth to an unconscious person. Only induce vomiting at the instruction of medical personnel. Get medical attention if any discomfort continues.

4.2. Most important symptoms and effects, both acute and delayed Irritation of eyes. Sensitisation. Symptoms may be delayed.

4.3. Indication of any immediate medical attention and special treatment needed Treat symptomatically.

SECTION 5: Firefighting measures

General fire hazards The product is not flammable. Will burn if involved in a fire.

5.1. Extinguishing media

Suitable extinguishing media Use fire-extinguishing media appropriate for surrounding materials.

Unsuitable extinguishing media None known.

5.2. Special hazards arising from the substance or mixture Dust may form explosive mixture with air. By heating and fire, toxic vapours/gases may be formed.

5.3. Advice for firefighters

Special protective equipment for firefighters Self-contained breathing apparatus and full protective clothing should be worn when fighting chemical fires. Selection of respiratory protection for firefighting: follow the general fire precautions indicated in the workplace.

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 contact with eyes, skin, and clothing. Avoid inhalation of dust. Wear suitable protective clothing. For personal protection, see Section 8 of the SDS.

For emergency responders Use personal protection recommended in Section 8 of the SDS. Keep unnecessary personnel away.

6.2. Environmental precautions Do not allow to enter drains, sewers or watercourses.

6.3. Methods and material for containment and cleaning up Sweep up or vacuum up spillage and collect in suitable container for disposal. After removal flush contaminated area thoroughly with water.

Never return spills to original containers for re-use.

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 Provide appropriate exhaust ventilation at places where dust is formed. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Avoid contact with skin and eyes. Avoid inhalation of dust. Wear appropriate personal protective equipment. Observe good industrial hygiene practices.

7.2. Conditions for safe storage, including any incompatibilities Store at 2-8°C (35-46°F). Store locked up. Store away from incompatible materials.

7.3. Specific end use(s) The IMUBIND Plasma PAI-1 ELISA is an enzyme-linked immunosorbent assay for the quantitative measurement of human Plasminogen Activator Inhibitor Type-1 (PAI-1) antigen in plasma.

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 Provide adequate ventilation. Observe Occupational Exposure Limits and minimise the risk of inhalation of dust. Provide easy access to water supply and eye wash facilities.

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 Use tight fitting goggles if dust is generated.

Skin protection

- Hand protection Wear protective gloves. Nitrile or neoprene gloves are recommended. Glove thickness approx 0.11 mm. Break through time > 480 min. Suitable gloves can be recommended by the glove supplier.

- Other Wear appropriate clothing to prevent repeated or prolonged skin contact.

Respiratory protection In case of inadequate ventilation or risk of inhalation of dust, use suitable respiratory equipment with particle filter (type P3).

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

Hygiene measures Handle in accordance with good industrial hygiene and safety practices. Wash hands after handling. Routinely wash work clothing and protective equipment to remove contaminants.

Environmental exposure controls Contain spills and prevent releases and observe national regulations on emissions.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Solid.
Physical state	Solid.
Form	Tablet.
Colour	Not available.
Odour	Not available.
Odour threshold	Not available.
pH	Not available.
Melting point/freezing point	258 °C (496.4 °F)
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not applicable.
Flammability (solid, gas)	Not available.
Vapour pressure	Not applicable.
Vapour density	Not applicable.
Relative density	Not available.
Solubility(ies)	No data available.
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	Stable at normal conditions.
10.3. Possibility of hazardous reactions	Dust may form explosive mixture with air.
10.4. Conditions to avoid	Heat. Avoid generation and spreading of dust.
10.5. Incompatible materials	Strong oxidising agents.
10.6. Hazardous decomposition products	Nitrogen oxides. Carbon oxides. Hydrogen chloride.

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	Dust in the eyes will cause irritation.
Ingestion	Harmful if swallowed.

Symptoms Irritation of eyes. Sensitisation. Symptoms may be delayed.

11.1. Information on toxicological effects

Acute toxicity	Harmful if swallowed.
Skin corrosion/irritation	Dust may irritate skin.
Serious eye damage/eye irritation	Causes severe eye irritation.
Respiratory sensitisation	No data available.
Skin sensitisation	May cause an allergic skin reaction.
Germ cell mutagenicity	Suspected of causing genetic defects.
Carcinogenicity	Suspected of causing cancer.
Reproductive toxicity	No data available.
Specific target organ toxicity - single exposure	No data available.
Specific target organ toxicity - repeated exposure	No data available.
Aspiration hazard	No data available.
Mixture versus substance information	Not available.
Other information	No other specific acute or chronic health impact noted.

SECTION 12: Ecological information

12.1. Toxicity	Very toxic to aquatic life with long lasting effects.
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	No data available.
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 of in accordance with local regulations.
Contaminated packaging	Since emptied containers retain product residue, follow label warnings even after container is emptied.
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. Do not discharge into drains, water courses or onto the ground.

SECTION 14: Transport information

ADR

14.1. UN number	UN3077
14.2. UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (o-Phenylenediamine dihydrochloride)

14.3. Transport hazard class(es)

Class 9
Subsidiary risk -
Label(s) 9
Hazard No. (ADR) 90
Tunnel restriction code E

14.4. Packing group III**14.5. Environmental hazards** Yes**14.6. Special precautions for user** Read safety instructions, SDS and emergency procedures before handling.**RID****14.1. UN number** UN3077**14.2. UN proper shipping name** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (o-Phenylenediamine dihydrochloride)**14.3. Transport hazard class(es)**

Class 9
Subsidiary risk -
Label(s) 9

14.4. Packing group III**14.5. Environmental hazards** Yes**14.6. Special precautions for user** Read safety instructions, SDS and emergency procedures before handling.**ADN****14.1. UN number** UN3077**14.2. UN proper shipping name** Environmentally Hazardous Solid, n.o.s. (o-Phenylenediamine dihydrochloride)**14.3. Transport hazard class(es)**

Class 9
Subsidiary risk -
Label(s) 9

14.4. Packing group III**14.5. Environmental hazards** Yes**14.6. Special precautions for user** Read safety instructions, SDS and emergency procedures before handling.**IATA****14.1. UN number** UN3077**14.2. UN proper shipping name** Environmentally hazardous substance, solid, n.o.s. (o-Phenylenediamine dihydrochloride)**14.3. Transport hazard class(es)**

Class 9
Subsidiary risk -
Label(s) 9

14.4. Packing group III**14.5. Environmental hazards** Yes**ERG Code** 9L**14.6. Special precautions for user** Read safety instructions, SDS and emergency procedures before handling.**IMDG****14.1. UN number** UN3077**14.2. UN proper shipping name** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (o-Phenylenediamine dihydrochloride)**14.3. Transport hazard class(es)**

Class 9
Subsidiary risk -
Label(s) 9

14.4. Packing group III**14.5. Environmental hazards****Marine pollutant** Yes**EmS** F-A, S-F**14.6. Special precautions for user** Read safety instructions, SDS and emergency procedures before handling.

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

o-Phenylenediamine dihydrochloride (CAS 615-28-1)

Other EU regulations

Directive 2012/18/EU on major accident hazards involving dangerous substances

o-Phenylenediamine dihydrochloride (CAS 615-28-1)

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

o-Phenylenediamine dihydrochloride (CAS 615-28-1)

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

o-Phenylenediamine dihydrochloride (CAS 615-28-1)

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 as amended.

National regulations

Follow national regulation for work with chemical agents. 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. Pregnant women should not work with the product, if there is the least risk of exposure.

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

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

H301 Toxic if swallowed.
H312 Harmful in contact with skin.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H332 Harmful if inhaled.
H341 Suspected of causing genetic defects.
H351 Suspected of causing cancer.
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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