>BIOMFDICA

SAFETY DATA SHEET

1. Identification

Product identifier Assay Diluent

Other means of identification

Product code Assay diluent, in 827 IMUBIND® Factor VIIa ELISA

Recommended use Research use only.

Recommended restrictions Use in accordance with supplier's recommendations.

Manufacturer/Importer/Supplier/Distributor information

Corporate Headquarters BioMedica Diagnostics Inc.

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7 cblf UWhbi a VYf MIS9591327

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Skin corrosion/irritation Category 2

> Serious eye damage/eye irritation Category 2 Sensitization, respiratory Category 1 Sensitization, skin Category 1

OSHA defined hazards Not classified.

Label elements



Signal word Danger

Hazard statement Causes skin irritation. Causes serious eye irritation. May cause allergy or asthma symptoms or

breathing difficulties if inhaled. May cause an allergic skin reaction.

Precautionary statement

Prevention Wash thoroughly after handling. Wear protective gloves/eye protection/face protection.

If on skin: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Response

Take off contaminated clothing and wash before reuse. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a

poison center/doctor.

Storage Store away from incompatible materials.

None known.

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

Hazard(s) not otherwise

classified (HNOC)

Supplemental information

Not applicable.

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3. Composition/information on ingredients

Mixtures

Chemical name	CAS number	%
Calcium chloride	10043-52-4	20-30
Sodium chloride	7647-14-5	20-30
2-Amino-2-(hydroxymethyl)pro pane-1,3-diol hydrochloride	1185-53-1	10-15
Tris-(hydroxymethyl)aminomet hane	77-86-1	1-3
Gentamicin sulfate	1405-41-0	0.1-<1

Composition comments

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

4. First-aid measures

Inhalation Move to fresh air. Call a physician if symptoms develop or persist.

Remove contaminated clothing. Wash with plenty of soap and water. If skin irritation occurs: Get Skin contact

medical advice/attention. Wash contaminated clothing before reuse.

Do not rub eyes. Immediately flush eyes with plenty of water for at least 15 minutes. Remove Eye contact

contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation

May cause redness and pain. Symptoms of overexposure may be headache, dizziness, tiredness,

develops and persists.

nausea and vomiting.

Rinse mouth. Get medical attention if symptoms occur. Ingestion

Most important

symptoms/effects, acute and

delaved Indication of immediate

medical attention and special treatment needed

Provide general supportive measures and treat symptomatically.

Ensure that medical personnel are aware of the material(s) involved, and take precautions to **General information** protect themselves. If you feel unwell, seek medical advice (show the label where possible).

5. Fire-fighting measures

Suitable extinguishing media

Unsuitable extinguishing

media

Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2). Do not use water jet as an extinguisher, as this will spread the fire.

Specific hazards arising from the chemical

Special protective equipment

and precautions for firefighters

equipment/instructions

During fire, gases hazardous to health may be formed.

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting

General fire hazards

Use standard firefighting procedures and consider the hazards of other involved materials.

No unusual fire or explosion hazards noted. Will burn if involved in a fire.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate protective equipment and clothing during clean-up. Avoid inhalation of dust. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Collect dust using a vacuum cleaner equipped with HEPA filter. Stop the flow of material, if this is without risk.

Large Spills: Wet down with water and dike for later disposal. Shovel the material into waste container. Following product recovery, flush area with water.

Small Spills: Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the SDS.

Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

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7. Handling and storage

Precautions for safe handling Minimize dust generation and accumulation. Provide appropriate exhaust ventilation at places

where dust is formed. Avoid breathing dust. Avoid contact with eyes, skin, and clothing. Wear appropriate personal protective equipment. Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities Store in a well-ventilated place. Store away from incompatible materials (see Section 10 of the

SDS).

8. Exposure controls/personal protection

Occupational exposure limits

No exposure limits noted for ingredient(s).

Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering

controls

Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. If material is ground, cut, or used in any operation which may generate dusts, use appropriate local exhaust ventilation to keep exposures below the recommended exposure limits. Eye wash facilities and emergency shower must be available when handling this product.

Individual protection measures, such as personal protective equipment

Eye/face protection

Wear safety goggles and a face shield.

Skin protection

Hand protection Wear appropriate chemical resistant gloves. Suitable gloves can be recommended by the glove

supplier.

Other

Wear appropriate chemical resistant clothing.

Respiratory protection

In case of inadequate ventilation or risk of inhalation of dust or fumes, use suitable respiratory

equipment.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective

equipment to remove contaminants.

9. Physical and chemical properties

Appearance

Solid. Physical state Powder. **Form** Color White.

Odor Not available. **Odor threshold** Not available. Not available. pН Melting point/freezing point Not available. Initial boiling point and boiling Not available.

range

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.

(%)

Not available. Vapor pressure Not available. Vapor density Relative density Not available.

Solubility(ies)

Solubility (water) Soluble in water. Partition coefficient Not available.

(n-octanol/water)

Auto-ignition temperature Not available. Not available. **Decomposition temperature** Not available. **Viscosity**

10. Stability and reactivity

Reactivity The product is stable and non-reactive under normal conditions of use, storage and transport.

Material is stable under normal conditions. Chemical stability Possibility of hazardous Hazardous polymerization does not occur.

reactions

Conditions to avoid Keep away from heat.

Incompatible materials Strong acids. Strong oxidizing agents. Reducing agents.

Hazardous decomposition

products

Carbon oxides. Nitrogen oxides.

11. Toxicological information

Information on likely routes of exposure

Inhalation Dust may irritate respiratory system.

Skin contact Causes skin irritation.

Eye contact Causes serious eye irritation.

Ingestion Harmful if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics Symptoms of overexposure may be headache, dizziness, tiredness, nausea and vomiting. May

cause redness and pain.

Information on toxicological effects

Acute toxicity

Test Results Components **Species**

Calcium chloride (CAS 10043-52-4)

Acute Oral

LD50 Rabbit 1000 mg/kg

Sodium chloride (CAS 7647-14-5)

Acute Dermal

LD50 Rabbit > 10000 mg/kg

Oral

LD50 Rat > 3980 mg/kg

Other

LD50 Mouse 2602 mg/kg

Tris-(hydroxymethyl)aminomethane (CAS 77-86-1)

Acute

Oral

LD50 Rat 5900 mg/kg

Skin corrosion/irritation Causes skin irritation.

Serious eye damage/eye Causes serious eye irritation.

irritation

Respiratory or skin sensitization

Respiratory sensitization May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Skin sensitization May cause an allergic skin reaction.

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are

mutagenic or genotoxic.

Not classifiable as to carcinogenicity to humans. Carcinogenicity

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

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Reproductive toxicityThis product is not expected to cause reproductive or developmental effects.

Specific target organ toxicity -

single exposure

Not classified.

Specific target organ toxicity -

repeated exposure

Not classified.

Aspiration hazard Not classified.

Aspiration nazaru Not ciassined.

Further information No other specific acute or chronic health impact noted.

12. Ecological information

Ecotoxicity 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.

Components Species Test Results

Sodium chloride (CAS 7647-14-5)

Aquatic

Crustacea EC50 Water flea (Daphnia magna) 874 mg/l, 48 hours

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

Tris-(hydroxymethyl)aminomethane (CAS 77-86-1) -2.31 (20°C)

Mobility in soil No data available.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation

potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructionsCollect and reclaim or dispose in sealed containers at licensed waste disposal site. Dispose of

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

Hazardous waste code

The waste code should be assigned in discussion between the user, the producer and the waste

disposal company.

Waste from residues / unused

products

Dispose of in accordance with local 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.

Since emptied containers may retain product residue, follow label warnings even after container is

emptied.

14. Transport information

DOT

Not regulated as dangerous goods.

ΙΑΤΑ

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to

Annex II of MARPOL 73/78 and

the IBC Code

15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication

Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not applicable.

Not listed.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

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Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes

Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous Yes

chemical

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act

Not regulated.

(SDWA)

US state regulations

US. Massachusetts RTK - Substance List

Not regulated.

US. New Jersey Worker and Community Right-to-Know Act

Not listed

US. Pennsylvania Worker and Community Right-to-Know Law

Not listed.

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

^{*}A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 01-December-2017
Revision date 17-July-2017

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A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

NFPA ratings



References

ACGIH

HSDB® - Hazardous Substances Data Bank

IARC Monographs. Overall Evaluation of Carcinogenicity

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