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	Thrombomodulin Standard, Thrombomodulin Control
Registration number	-
Synonyms	None.
Product code	Thrombomodulin standard & control, in 837 IMUBIND® Thrombomodulin ELISA
Issue date	01-December-2017
Version number	02
Revision date	18-July-2017
Supersedes date	20-July-2015

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

Identified uses	Research 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

Serious eye damage/eye irritation	Category 2	H319 - Causes serious eye irritation.

Hazard summary Causes serious eye irritation. Contains a small concentration of ingredients that may produce an allergic reaction.

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.

Precautionary statements

Prevention

P264	Wash hands thoroughly after handling.
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 Store away from incompatible materials.

Disposal Dispose of waste and residues in accordance with local authority requirements.

Supplemental label information EUH208 - Contains Gentamicin sulfate. May produce an allergic reaction.

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
Sodium chloride	30 - 40	7647-14-5 231-598-3	01-2119485491-33-XXXX	-	
Classification: -					
Disodium hydrogen orthophosphate	5 - 10	7558-79-4 231-448-7	-	-	
Classification: Eye Irrit. 2;H319					
Ethylenediaminetetraacetic acid trisodium salt	5 - 10	85715-60-2 -	-	-	
Classification: Eye Irrit. 2;H319					
Gentamicin sulfate	0.1 - <1	1405-41-0 215-778-9	-	-	
Classification: Skin Irrit. 2;H315, Skin Sens. 1;H317, Eye Irrit. 2;H319, Resp. Sens. 1;H334					

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. If breathing is difficult, give oxygen. Get medical attention if any discomfort continues.

Skin contact For skin contact flush with large amounts of water while removing contaminated clothing. 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 if dust is ingested. Get medical advice/attention if you feel unwell.

4.2. Most important symptoms and effects, both acute and delayed Contact with this material can cause irritation to the skin, eyes and mucous membranes. Headaches, nausea and vomiting. Dermatitis.

4.3. Indication of any immediate medical attention and special treatment needed Provide general supportive measures and treat symptomatically.

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.

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	Keep unnecessary personnel away. See Section 8 of the SDS for Personal Protective Equipment.
For emergency responders	Use personal protection recommended in Section 8 of the SDS.
6.2. Environmental precautions	Avoid discharge into drains, water courses or onto the ground.
6.3. Methods and material for containment and cleaning up	Avoid dust formation. Sweep or scoop up and remove.
6.4. Reference to other sections	For waste disposal, see Section 13 of the SDS.

SECTION 7: Handling and storage

7.1. Precautions for safe handling	Avoid prolonged exposure. Persons susceptible for allergic reactions should not handle this product. Observe good laboratory hygiene practices. Avoid inhalation of dust and contact with skin and eyes. The source material for this product is of human origin and has been found to be non-reactive for Hepatitis B Surface Antigen (HBsAg), Hepatitis C Virus (HCV) and Human Immunodeficiency Virus Type 1 and Type 2 (HIV-1, HIV-2) using registered methods. As no known test method can provide complete assurance that products derived from human specimens will not transmit HBsAg, HCV, HIV-1, HIV-2 or other blood-borne pathogens, this reagent should be handled as recommended for any potentially infectious human specimen.
7.2. Conditions for safe storage, including any incompatibilities	Store at 2 - 8°C. Store in a closed container away from incompatible materials.
7.3. Specific end use(s)	Research use only.

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	No special ventilation requirements.

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 dust-resistant safety goggles.
Skin protection	
- Hand protection	Wear protective gloves. Chemical resistant gloves are recommended.
- Other	It is a good industrial hygiene practice to minimise skin contact.
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

Physical state	Solid.
Form	Lyophylized powder.
Colour	White.
Odour	Not available.
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 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)	Water soluble.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Explosive properties	Not explosive.
Oxidizing properties	Not oxidising.
9.2. Other information	No relevant additional information available.

SECTION 10: Stability and reactivity

10.1. Reactivity	Stable at normal conditions.
10.2. Chemical stability	Material is stable under normal conditions.
10.3. Possibility of hazardous reactions	Polymerization will not occur.
10.4. Conditions to avoid	Keep away from heat.
10.5. Incompatible materials	Strong oxidising agents. Strong reducing agents. Strong acids.
10.6. Hazardous decomposition products	Carbon oxides. Nitrogen oxides.

SECTION 11: Toxicological information

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	Contact with this material can cause irritation to the skin, eyes and mucous membranes. Headaches, nausea and vomiting. Dermatitis.

11.1. Information on toxicological effects

Acute toxicity	May cause discomfort if swallowed.

Components	Species	Test results
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

Skin corrosion/irritation Dust may irritate skin.

Serious eye damage/eye irritation Causes serious eye irritation.

Respiratory sensitisation Not classified. The product contains a small amount of sensitising substance which may provoke an allergic reaction among sensitive individuals.

Skin sensitisation Not classified. The product contains a small amount of sensitising substance which may provoke an allergic reaction among sensitive individuals.

Germ cell mutagenicity Not classified.

Carcinogenicity Not classified.

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 Not available.

SECTION 12: Ecological information

12.1. Toxicity 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

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 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. Contaminated instruments and surfaces should be disinfected in accordance with your employer's chemical-specific and universal/standard precautions.

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

Not listed.

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

Not listed.

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

Not listed.

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. In the European Union this product is regulated under the In Vitro Diagnostic Medical Devices Directive (98/79/EC).

National regulations

Follow national regulation for work with chemical agents.

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	H315 Causes skin irritation. H317 May cause an allergic skin reaction. H319 Causes serious eye irritation. H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Training information	Follow training instructions when handling this material.
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