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

1.1. Product identifier
Trade name or designation of the mixture: Anti-(h)-D-dimer-HRP conjugate
Registration number: -
Synonyms: None.
Product code: 602
Issue date: 01-December-2017
Version number: 02
Revision date: 13-July-2017
Supersedes date: 30-September-2015

1.2. Relevant identified uses of the substance or mixture and uses advised against
Identified uses: Use in accordance with supplier’s recommendations.
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
This mixture does not meet the criteria for classification according to Regulation (EC) 1272/2008 as amended.

Hazard summary: Exposure to powder or dusts may be irritating to eyes, nose and throat.

2.2. Label elements

Label according to Regulation (EC) No. 1272/2008 as amended
Hazard pictograms: None.
Signal word: None.
Hazard statements: None.

Precautionary statements

Prevention: Observe good laboratory hygiene practices.
Response: Wash with plenty of water.
Storage: Store away from incompatible materials.
Disposal: Dispose of waste and residues in accordance with local authority requirements.

Supplemental label information: Not applicable.

2.3. Other hazards
Not a PBT or vPvB substance or mixture.
SECTION 3: Composition/information on ingredients
3.2. Mixtures
The components are not hazardous or are below required disclosure limits.

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
Dusts may irritate the respiratory tract, skin and eyes.

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
Carbon dioxide and carbon monoxide.

5.3. Advice 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.

SECTION 6: Accidental release measures
6.1. Personal precautions, protective equipment and emergency procedures
For non-emergency personnel
No special precautions are necessary beyond normal good hygiene practices. See Section 8 of the SDS for additional personal protection advice when handling this product.

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
Sweep or scoop up and remove.

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
No specific recommendations due to the small quantities handled. However: Avoid contact with skin and eyes. Wash thoroughly after handling. Observe good laboratory hygiene practices.

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

7.3. Specific end use(s)
Not available.

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
No special ventilation requirements.

Appropriate engineering controls
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
No protection is ordinarily required under normal conditions of use. Risk of contact: Wear dust-resistant safety goggles.

Skin protection
- Hand protection
It is a good industrial hygiene practice to minimise skin contact.
- Other
It is a good industrial hygiene practice to minimise skin contact.

Respiratory protection
No specific recommendations due to the small quantities handled.

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
Lyophilised powder.
Colour
Not available.
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)
Not 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
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
Avoid dust formation.

10.5. Incompatible materials
None known.

10.6. Hazardous decomposition products
Carbon oxides. Nitrogen oxides.

SECTION 11: Toxicological information

Information on likely routes of exposure

Inhalation
Due to the small packaging the risk of inhalation is minimal. However: Dust may irritate respiratory system.

Skin contact
No adverse effects due to skin contact. However: May cause irritation through mechanical abrasion.

Eye contact
Direct contact may irritate.

Ingestion
No adverse effects due to ingestion are expected. However: May cause discomfort if swallowed.

Symptoms
Dusts may irritate the respiratory tract, skin and eyes.

11.1. Information on toxicological effects

Acute toxicity
Because of quantity and composition, the health hazard is small.

Skin corrosion/irritation
Not classified.

Serious eye damage/eye irritation
Not classified.

Respiratory sensitisation
Not classified.

Skin sensitisation
Not classified.

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
Frequent inhalation of dust over a long period of time increases the risk of developing lung diseases. Because of quantity and composition, the health hazard is small.

SECTION 12: Ecological information

12.1. Toxicity
Not relevant considering the small amounts used.

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 and the IBC Code

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.
  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.
  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

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.

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
None.

Training information
Follow training instructions when handling this material.

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