

INF112/3.1 – Safety Data Sheet NHSBT Monoclonal Antibody Reagents

According to EC Regulations 1907/2006 (REACH),
1272/2008 (CLP) & 2015/830



Blood and Transplant

Copy No:

Effective date: 22/11/2024

Safety Data Sheet

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

1.1 Product identifier

BRAD-3 and AEVZ 5.3 FITC conjugates and BIRMA 17C Phycoerythrin conjugate

Product Code	Product Name	UDI-DI
9442FI	AEVZ 5.3 FITC conjugated control reagent	5055232400444
9433FI	BRAD 3 FITC Conjugated Anti-RhD Reagent	5055232400437
9453PE	BIRMA 17C PE Conjugated Control Reagent	5055232400451

CAS No. : Mixtures

EC No. : Mixtures

- 1.2 Relevant identified uses of the substance or mixture and uses advised against
Identified uses: BRAD-3 and AEVZ 5.3 monoclonal antibody FITC conjugates and BIRMA 17C monoclonal antibody Phycoerythrin (PE) conjugate are used for estimation of fetomaternal haemorrhage (FMH) by flow cytometry. For *in-vitro* diagnostic use only
Uses advised against: Anything other than the above
- 1.3 Details of the supplier of the safety data sheet
NHSBT Reagents, 14 Estuary Banks, Speke, Liverpool, L24 8RB. United Kingdom,
Telephone: 0151 268 7157
Fax: 0151 268 7156
Email: reagents@nhsbt.nhs.uk
- 1.4 Emergency telephone number
NHSBT Reagents customer services 0151 268 7157 (Monday to Friday 9am to 5pm. Calls will be forwarded to an answering machine outside of these hours)
Further information available from: www.blood.co.uk/reagents
Languages spoken: English

Devices prepared at:

Protein Development and Production Unit (PDPU),
International Blood Group Reference Laboratory,
North Bristol Park,
Filton,
Bristol. BS34 7QH
United Kingdom.
Telephone: 0117 921 7592
Email: enquiries.IBGR@nhsbt.nhs.uk
<http://ibgrl.blood.co.uk>

Devices tested at:

NHSBT Reagents Liverpool,
14 Estuary Banks,
Speke,
Liverpool. L24 8RB.
United Kingdom.
Telephone: 0151 268 7157

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2 SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Not classified as hazardous for supply/use according to Regulation (EC) 1272/2008 (CLP).

2.2 Label elements

No Hazard Pictogram(s), Signal Word(s), Hazard Statement(s) or Precautionary Statement(s) have been assigned according to Regulation (EC) 1272/2008 (CLP).

2.3 Other hazards

Sodium azide is very toxic by inhalation, in contact with skin and if swallowed.

Contact with acid liberates very toxic gas.

Heating may cause explosion.

Readily absorbed through skin.

Avoid contact with metals, may react with lead and copper plumbing to form highly explosive metal azides.

However, the concentrations used within this reagent are not associated with any hazards

3 SECTION 3: Composition/information on ingredients

3.1 Substances

N/A

3.2 Mixtures

EBV transformed cells producing BRAD-3 purified anti-D human IgG3 monoclonal antibody FITC conjugated.

Antibody engineered NSO cells producing AEVZ 5.3 purified human IgG3 negative control monoclonal antibody FITC conjugated.

Hybridoma cells producing BIRMA 17C purified anti-CD66b (granulocytes) mouse IgG1 monoclonal antibody PE conjugated.

All reagents are supplied in phosphate buffered saline pH7.2 (PBS) containing the following:

Component	Approximate Concentration (%)	CAS number	EC number	Hazard
Bovine serum albumin	Varies	94349-60-7	305-179-1	Acute Tox. 4; H302: Harmful if swallowed.
Sodium azide	<0.1	26628-22-8	247-852-1	Acute Tox. 2; H300: Fatal if swallowed Aquatic Acute 1; H400: Very toxic to aquatic life Aquatic Chronic 1; H410: Very toxic to aquatic life with long lasting effects

None of the products at the concentration used within this reagent are associated with any hazards.

4 SECTION 4: First aid measures

4.1 Description of first aid measures

Eye contact: Flush eyes with water for at least 15 minutes while holding eyelids open. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical advice/attention.

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Skin contact: Wash affected skin with soap and water. Remove contaminated clothing and wash clothing before reuse. If irritation (redness, rash, blistering) develops, get medical attention.

Ingestion: Rinse mouth. Give plenty of water to drink. Do not give anything by mouth to an unconscious person. Get medical advice/attention if you feel unwell.

Inhalation: Not applicable.

- 4.2 Most important symptoms and effects, both acute and delayed
All known important symptoms are described in Section 3.
- 4.3 Indication of any immediate medical attention and special treatment needed
No special treatment indicated. Treat Symptomatically.

5 SECTION 5: Firefighting measures

- 5.1 Extinguishing media
Non-Flammable. Use extinguishing media appropriate to the surrounding conditions.
- 5.2 Special hazards arising from the substance or mixture
None known.
- 5.3 Advice for firefighters
Fight fire with normal precautions from a reasonable distance.

6 SECTION 6: Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures
Use personal protective equipment during removal of spillages.
- 6.2 Environmental precautions
Control spillage in accordance with local regulations.
- 6.3 Methods and material for containment and cleaning up
Absorb on sand or vermiculite and place in closed containers for disposal. Wash spill site after material pick up is complete. Spray spillage with appropriate detergent and absorb.
- 6.4 Reference to other sections
See section 8 and 13 for disposal information

7 SECTION 7: Handling and storage

- 7.1 Precautions for safe handling
When handling product use personal protective equipment as required. Wash hands thoroughly after handling. Contaminated clothing should be thoroughly cleaned.
Protect from contamination.
Protect from the light.
- 7.2 Conditions for safe storage, including any incompatibilities
Store the reagent at +2°C to +8°C in the original container/packaging.
Store in an amber bottle.
- 7.3 Specific end use(s)
See section 1.2

8 SECTION 8: Exposure controls/personal protection

- 8.1 Control parameters
None of the products at the concentration used within this reagent are associated with any hazards. No monitoring procedures required

8.2 Exposure controls

When handling product use personal protective equipment as required. Avoid contact. Keep good hygiene and housekeeping measures.

9 SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

- (a) Appearance: A tinted green liquid for FITC conjugates and a tinted pink liquid for PE conjugates
- (b) Odour: Odourless
- (c) Odour threshold: Not established
- (d) pH: Not established
- (e) Melting point/freezing point: Not established
- (f) Initial boiling point and boiling range: Not established
- (g) Flash point: Not established
- (h) Evaporation rate: Not established
- (i) Flammability (solid, gas): Not established
- (j) Upper/lower flammability or explosive limits: Not applicable
- (k) Vapour pressure: Not established
- (l) Vapour density: Not established
- (m) Relative density: Not established
- (n) Solubility(ies): Miscible with water
- (o) Partition coefficient: n-octanol/water: Not established
- (p) Auto-ignition temperature: Not established
- (q) Decomposition temperature: Not established
- (r) Viscosity: Not established
- (s) Explosive properties Not explosive
- (t) Oxidising properties: Not oxidising

9.2 Other information

No further information available

10 SECTION 10: Stability and reactivity

10.1 Reactivity

Stable under normal conditions

10.2 Chemical stability

Stable for stated expiry date of the product when stored between +2°C and +8°C.

Do not freeze

Protect from extremes of temperature.

Do not use if reagent exhibits turbid or if a precipitate, gel or particles are present.

Protect from the light.

10.3 Possibility of hazardous reactions

None under normal processing

10.4 Conditions to avoid

Keep away from heat and direct sunlight.

10.5 Incompatible materials

There are no known materials that could react with this product to produce a hazardous situation.

10.6 Hazardous decomposition products

There are no known hazardous decomposition products produced.

11 SECTION 11: Toxicological information

11.1 Information on toxicological effects

(a) acute toxicity;

Ingestion: based on available data, the classification criteria are not met for this mixture.

(b) skin corrosion/irritation; based on available data, the classification criteria are not met for this mixture.

(c) serious eye damage/irritation; based on available data, the classification criteria are not met for this mixture.

(d) respiratory or skin sensitisation; based on available data, the classification criteria are not met for this mixture.

(e) germ cell mutagenicity; based on available data, the classification criteria are not met for this mixture.

(f) carcinogenicity; based on available data, the classification criteria are not met for this mixture.

(g) reproductive toxicity; based on available data, the classification criteria are not met for this mixture.

(h) STOT-single exposure; based on available data, the classification criteria are not met for this mixture.

(i) STOT-repeated exposure; based on available data, the classification criteria are not met for this mixture.

(j) aspiration hazard: based on available data, the classification criteria are not met for this mixture.

See section 3 for individual component hazard classification.

12 SECTION 12: Ecological Information

12.1 Toxicity

Based on available data, the classification criteria are not met for this mixture. (see section 3 for individual component hazard classification)

12.2 Persistence and degradability

Not established. Predicted to be unlikely.

12.3 Bio accumulative potential

Not established. Predicted to be unlikely.

12.4 Mobility in soil

This product has high mobility in soil. Miscible with water.

12.5 Results of PBT and vPvB assessment

Not classified as PBT or vPvB. None of the substances in this product fulfil the criteria for being regarded as a PBT or vPvB substance.

12.6 Other adverse effects

None known.

13 SECTION 13: Disposal Considerations

13.1 Waste treatment methods

The product and any contaminated packaging should be disposed in accordance with local state or national legislation.

Waste disposal method is to dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

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14 SECTION 14: Transport Information

Not classified according to the United Nations 'Recommendations on the Transport of Dangerous Goods.'

- 14.1 UN number
Not assigned ADR/RID, IMDG or IATA/ICAO numbers.
- 14.2 UN proper shipping name
Not assigned ADR/RID, IMDG or IATA/ICAO numbers.
- 14.3 Transport hazard class(es)
Not assigned ADR/RID, IMDG or IATA/ICAO numbers.
- 14.4 Packing group
Not assigned ADR/RID, IMDG or IATA/ICAO numbers.
- 14.5 Environmental hazards
Not assigned ADR/RID, IMDG or IATA/ICAO numbers.
- 14.6 Special precautions for user
See section 2
- 14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code
Not Applicable

15 SECTION 15: Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
This product does not contain substances subject to EU authorisation or restriction of use.
This safety datasheet was prepared in accordance with the requirements of EC regulation 1907/2006 (REACH) (Article 32, Annex II) and 1272/2008 (CLP) & 2015/830
- 15.2 Chemical safety assessment
None.

16 Other information

Amendments from the previous version of this SDS are in purple text.

LEGEND	
ADR	Agreement concerning the International Carriage of Dangerous Goods by Road
CAS	Chemical abstracts service
CLP	Classification, labelling and packaging of substances and mixtures
EC	European Commission
EDTA	Ethylenediaminetetraacetic acid
IATA	International Air Transport Association
IBC	International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods
LC50	Lethal Concentration to 50% of a test population
LD50	Lethal Dose to 50% of a test population (Median Lethal Dose)
MARPOL	International Convention for the Prevention of Pollution from Ships

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OECD	Organisation for Economic Cooperation and Development
PBT	Persistent, Bio accumulative and Toxic
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety data sheet
STOT	Specific target organ toxicity
vPvB	Very persistent and very bio accumulative

Disclaimers

Customers are urged to ensure that the product is entirely suitable for their own purpose. It is the customers' responsibility to ensure that a suitable and sufficient assessment of the risks created by the use of the product is undertaken. The use of the reagent and the interpretation of results must be conducted by professionally trained and qualified personnel in accordance with the requirements of the country where the reagent is in use.

Information contained in this publication or as otherwise supplied to Users is believed to be accurate and is given in good faith, but it is for the Users to satisfy themselves of the suitability of the product for their own particular purpose. NHSBT reagents gives no warranty as to the fitness of the product for any particular purpose and any implied warranty or condition (statutory or otherwise) is excluded except to the extent that exclusion is prevented by law. NHSBT reagents accepts no liability for loss or damage (other than that arising from death or personal injury caused by defective product, if proved), resulting from reliance on this information. Freedom under Patents, Copyright and Designs cannot be assumed.

Training advice

Consideration should be given to the work procedures involved and the potential extent of exposure as they may determine whether a higher level of protection is required.

Date of First Issue

07/11/2008