Safety Data Sheet

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

1.1 Product identifier

Red Cell Reagents in CellMedia

Product Code	Product Name	UDI-DI
PR162, PR163	ID Panel cells	5055232400307, 5055232400291
PR172, PR173	Papainised ID Panel	5055232400369, 5055232400352
PR015	A_1rr cell	5055232400086
PR036	Brr cell	5055232400109
PR046	OR1r cell	5055232400130
PR103	2 cell antibody screening cells	5055232400161
PR123	3 cell antibody screening cells	5055232400192
PR108	rr antibody screen	5055232400239
PN109	r'r, r"r antibody screen	5055232400246

CAS No. : Mixtures
EC No. : Mixtures

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

Identified uses: Human red cell reagents 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

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

DG CellMedia solution contains no known hazardous material.

The donations used in this product are of human origin. They have been tested and found negative for the mandatory microbiological tests required by the UK guidelines for blood

transfusion services during donation testing. No known test methods can offer assurances that products derived from human blood will not transmit infectious diseases. This device should be treated as clinical material for its use and disposal.

3 SECTION 3: Composition/information on ingredients

3.1 Substances

N/A

3.2 Mixtures

Donated human red cells as a 0.8% cell suspension in DG CellMedia which is buffered saline supplied by Grifols and contains as a minimum:

Component	Approximate Concentration (%)	CAS number	EC number	Hazard
Glycine	<100	56-40-6	200-272-2	No hazards
Sodium chloride	<100	7647-14-5	231-598-3	No hazards
Glucose	<100	50-99-7	200-075-1	No hazards
Ethylenediaminetetraacetic acid	<1	60-00-4	200-449-4	Eye Irrit. 2; H319: Causes serious eye irritation.
Chloramphenicol	<0.1	56-75-7	200-847-4	Eye Damage 1; H318: Causes serious eye damage Repr. 2; H361: Suspected of damaging fertility or the unborn child Carc. 2; H351: Suspected of causing cancer
Neomycin sulphate	<0.1	1405-10-3	215-773-1	Skin Sens. 1; H317: May cause an allergic skin reaction. Resp. Sens. 1; H335 May cause respiratory irritation. H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled. Aquatic Chronic 3; H412: Harmful 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.

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

Spray spillage with appropriate virucidal detergent and absorb in suitable inert material, wash spill site after material pick up is complete.

6.4 Reference to other sections

See sections 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.

7.2 Conditions for safe storage, including any incompatibilities

Store the reagent at +2°C to +8°C in the original container/packaging.

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 suspension of red cells in a clear liquid.
(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 obvious discolouration or haemolysis.

10.3 Possibility of hazardous reactions
None under normal processing and use.

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, but as the product is derived from human blood it should be treated as potentially infectious and be disposed of appropriately.

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

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

12.1 Persistence and degradability
Not established. Predicted to be unlikely.

12.2 Bio accumulative potential
Not established. Predicted to be unlikely.

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

12.4 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.

12.5 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.

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 SECTION 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
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.

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