

# INF82/3 – Safety Data Sheet NHSBT

## Reagents Papainised Allo-absorption Cells & Papainised Quantification Cells

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



Blood and Transplant

Copy No:

Effective date:

22/09/2023

### Safety Data Sheet

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

### 1.1 Product identifier

Human red cell reagents.

Product Code	Product Name	UDI-DI
PR404	Papainised alloabsorption OR1R1 and Orr cells	5055232400512
PR405	Papainised Alloabsorption OR2R2 cells	5055232400505
PR408	Papainised Cells for Quantification - OR1R1 cells	5055232400529
PR409	Papainised Cells for Quantification - Orr cells	5055232400536

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](http://www.blood.co.uk/reagents)

Languages spoken: English

## 2 SECTION 2: Hazard 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

Alsevers solution (S104-320) contains chloramphenicol (0.34g/L) which is classified as a carcinogen and neomycin sulphate (0.1g/L) which is classified as an irritant when used neat but at the concentration used within this reagent are not associated with any hazards.

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

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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

Papain treated donated human red cells as a 30% (alloabsorption cells) or 25% (Quantification cells) suspension in Modified Alsevers solution containing the following:

Component	Approximate Concentration (%)	CAS number	EC number	Hazard
D glucose	2	50-99-7	200-075-1	No hazards
Trisodium citrate	0.8	68-04-2	200-675-3	No hazards
Sodium chloride	0.42	7647-14-5	231-598-3	No hazards
Inosine	0.0938	58-63-9	200-390-4	No hazards
Citric acid monohydrate	0.05	5949-29-1	201-069-1	Eye Irrit. 2; H319: Causes serious eye irritation. STOT SE 3; H335: May cause respiratory irritation.
Adenosine 5-triphosphate disodium salt	0.04	56-65-5	200-283-2	No hazards
Chloramphenicol	0.034	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	0.01	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;

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				H412: Harmful to aquatic life with long lasting effects.
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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

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### 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

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### 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

### 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.

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- 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.

### 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

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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.

### Date of First Issue

18/07/2008

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