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: human plasma, liquid
Registration number: -
Synonyms: depleted human plasma
Product code: ADG204, ADG218
Issue date: 16.03.2015
Version number: 01
Revision date: -
Supersedes date: -

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
Manufacturer/Distributor: Sekisui Diagnostics GmbH
Address: Kaplaneigasse 35, D-64319 Pfungstadt, Germany
Telephone number: +49 (0) 6157-990899
Website: www.sekisuidiagnostics.com
Contact person: Martina Klöppinger
E-mail: questions@sekisuidiagnostics.com

1.4. Medical Emergency information in case of poisoning:
Poison Information Center Mainz
(Advisory service in German or English language) Phone: +49 (0) 6131 19240

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 Directive 67/548/EEC or 1999/45/EC as amended
This preparation is not classified as dangerous according to Directive 1999/45/EC and its amendments.

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
Physical hazards: Not classified for physical hazards.
Health hazards: Not classified for health hazards.
Environmental hazards: Not classified for hazards to the environment.
Specific hazards: Avoid contact with eyes and skin. Do not ingest or inhale.
Main symptoms: Direct contact with skin and eyes may cause irritation.

2.2. Label elements

human plasma, liquid
Version #: 01 Revision date:----------- Issue date: 16.03.2015 SDS EU page 1 /7
Label according to Regulation (EC) No. 1272/2008 as amended

Contains: human plasma

Hazard pictograms None.

Signal word None.

Hazard statements The mixture does not meet the criteria for classification.

Precautionary statements

Prevention None.

Response None.

Storage None.

Disposal None.

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

General information

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>%</th>
<th>CAS-No. / EC No.</th>
<th>REACH Reg. No.</th>
<th>INDEX No.</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human plasma</td>
<td>&lt; 100</td>
<td>N/A</td>
<td>-</td>
<td>613-167-00-5</td>
<td>-</td>
</tr>
</tbody>
</table>

Classification: DSD: -
CLP: -

List of abbreviations and symbols that may be used above

DSD: Directive 67/548/EEC.


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 R- and H-phrases 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. Call a physician if symptoms develop or persist.

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 ingested. Get medical advice/attention if you feel unwell.

4.2. Most important symptoms and effects, both acute and delayed

May cause skin, eye and respiratory tract irritation.

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

The product is not flammable.

5.1. Extinguishing media

Suitable extinguishing media

Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the surrounding fire.
5.2. Special hazards arising from the substance or mixture

None known.

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.

Special protective equipment for firefighters

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

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 as recommended in section 8 of the SDS.

6.2. Environmental precautions

Avoid discharge into drains, water courses or into the ground.

6.3. Methods and material for containment and cleaning up

Absorb spill with vermiculite or other inert material. Dispose of waste in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.

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

Avoid prolonged exposure. Avoid 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. Observe good laboratory hygiene practices.

7.2. Conditions for safe storage, including any incompatibilities

Store at -20°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.

Exposure guidelines

Follow standard monitoring procedures.

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
- It is a good industrial hygiene practice to minimise skin contact.
  - Wear safety glasses or goggles.

Skin protection
- Hand protection
  - It is a good industrial hygiene practice to minimise skin contact. Wear appropriate chemical resistant gloves.
- Other

Respiratory protection
- It is a good industrial hygiene practice to minimise skin contact.

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: Frozen solution.
- Form: Liquid
- Colour: Colourless-yellowish.
- Odour: None.
- Odour threshold: Not applicable.
- pH: 7.2-7.5
- Melting point/freezing point: Not available.
- Initial boiling point and range: Not relevant.
- Flash point: Not relevant.
- Evaporation rate: Not applicable.
- Flammability (solid, gas): Not flammable.

Upper/lower flammability or explosive limits
- Flammability limit - lower (%): Not available.
- Flammability limit - upper (%): Not available.
- Vapour pressure: Not relevant.
- Vapour density: Not relevant.
- Relative density: Not available.
- Solubility(ies): Soluble in water.
- Partition coefficient (n-octanol/water): Not available.
- Auto-ignition temperature: Not available.
- Decomposition temperature: Not available.
- Viscosity: Not relevant.
- Explosive properties: Not relevant.
- Oxidizing properties: Not oxidizing.

9.2. Other information
- No relevant additional information available.

SECTION 10: Stability and reactivity

10.1. Reactivity
- The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability
- Material is stable under normal conditions.

10.3. Possibility of hazardous reactions
- Hazardous polymerisation does not occur.
10.4. Conditions to avoid  Keep away from heat.

SECTION 11: Toxicological information

General information  Occupational exposure to the substance or mixture may cause adverse effects.

Information on likely routes of exposure

Inhalation  May irritate throat and respiratory system and cause coughing.
Skin contact  May cause skin irritation.
Eye contact  May cause eye irritation.
Ingestion  May cause discomfort if swallowed.

Symptoms  Mechanical irritation of skin, eyes and respiratory system.

11.1. Information on toxicological effects

Acute toxicity  May cause discomfort if swallowed.
Skin corrosion/irritation  May cause skin irritation.
Serious eye damage/eye irritation  May cause eye irritation.
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  Not available.

SECTION 12: Ecological information

12.1. Toxicity  No toxicity data noted for the ingredient(s).
12.2. Persistence and degradability  No data is available on the degradability of this product.
12.3. Bioaccumulative potential  Not available.
Partition coefficient  Not available.
n-octanol/water (log Kow)  Not available.
Bioconcentration factor (BCF)  Not available.
12.4. Mobility in soil  Not available.
Mobility in general  No data available.
12.5. Results of PBT and vPvB assessment  Not a PBT or vPvB substance or mixture.
12.6. Other adverse effects  Not 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:

Authorisations:

Restrictions on use:
Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding
Not listed.

Other EU regulations
Directive 96/82/EC (Seveso II) on the control of major-accident hazards involving dangerous substances
Not listed.

Directive 94/33/EC on the protection of young people at work
Not listed.

Other regulations
This product does not meet the criteria for classification according to Regulation (EC) 1272/2008 (CLP Regulation) and Directive 1999/45/EC and their amendments respectively. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006.

National regulations
The product has not been classified as dangerous according to the legislation in force.

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.
- PBT: Persistent, bioaccumulative and toxic.
- vPvB: Very Persistent and very Bioaccumulative.

References
- HSDB® - Hazardous Substances Data Bank

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 statements or R-phrases and H-statements under Sections 2 to 15
None.

Training information
Follow training instructions when handling this material.

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