1. Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier
Product Identity: Beriplast P Combi-Set 0.5/1/3 ml
Alternate Names: Beriplast P Combi-Set

1.2. Relevant identified uses of the substance or mixture and uses advised against
Intended use: See Technical Data Sheet.
Application Method: See Technical Data Sheet.

1.3. Details of the supplier of the safety data sheet
Company Name: CSL Behring L.L.C.
1020 First Avenue
PO Box 61501
King of Prussia, PA
Emergency
24 hour Emergency Telephone No.
Emergency Response: (800) 424-9300
Emergency Product Information: (800) 504-5434
Customer Service: CSL Behring L.L.C.
(610) 878-4000

2. Hazard identification of the product

2.1. Classification of the substance or mixture
Classification according to Regulation (EC) No 1272/2008
No applicable CLP categories.
Classification according to 67/548/EEC or 1999/45/EC.
No applicable DPD categories.

2.2. Label elements
Using the Toxicity Data listed in section 11 and 12 the product is labeled as follows.

According to Regulation (EC) No 1272/2008
[Prevention]:
No CLP prevention statements
[Response]:
No CLP response statements
[Storage]:
No CLP storage statements
[Disposal]:
No CLP disposal statements
See Technical Data Sheet.

2.3. Other hazards
This product contains no PBT/vPvB chemicals.
3. Composition/information on ingredients

There are no ingredients in this product which are classified as hazardous, and/or no hazardous ingredients above the GHS cut off percentage.

Non-Hazardous Ingredients:
Material: Medicinal product (Fibrin Sealant Kit)

Active ingredient: Combi Set 1:
Vial 1: Human Fibrinogen Concentrate (Factor I and Factor XIII)
Vial 2: Bovine Aprotinin Solution

Combi Set 2:
Vial 3: Human Thrombin
Vial 4: Calcium Chloride Solution (under declaration concentration)

Other components: Vial 1: Albumin, Aminoacids, Sodium chloride (non-hazardous components)
Vial 2: Sodium chloride, Water for injection
Vial 3: Sodium chloride, Sodium citrate
Vial 4: Water for injection

Packaging units: 1 package of Beriplast® P Combi-Set consists of 4 premounted vials and 1 application kit for joint application

4. First aid measures

4.1. Description of first aid measures

General
Take off and remove dirty clothes.

Inhalation
Remove to fresh air.

Eye
Irrigate copiously with clean water for at least 15 minutes, holding the eyelids apart and seek medical attention.

Skin
Remove contaminated clothing. Wash skin thoroughly with soap and water or use a recognized skin cleanser.

Ingestion
Drink water. Obtain medical attention if feeling ill.

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

Overview
No specific symptom data available.

5. Fire-fighting measures

5.1. Extinguishing media
As suitable for surrounding fire.

5.2. Special hazards arising from the substance or mixture
Hazardous decomposition: No hazardous decomposition data available.

5.3. Advice for fire-fighters
None
6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures
Put on appropriate personal protective equipment (see section 8).

6.2. Environmental precautions
Do not allow spills to enter drains or waterways.
Use good personal hygiene practices. Wash hands before eating, drinking, smoking or using toilet. Promptly remove soiled clothing and wash thoroughly before reuse.

6.3. Methods and material for containment and cleaning up
Collect/absorb spilled material and dispose of properly.

7. Handling and storage

7.1. Precautions for safe handling
General precautions for handling of pharmaceuticals are to be considered. Protect from light when handling.

7.2. Conditions for safe storage, including any incompatibilities
Handle containers carefully to prevent damage and spillage.
Storage and transportation temperatures should not fall below 2C and not exceed 8C.
Incompatible materials: No data available.
Keep container closed tightly.
Store locked up or accessible to authorized persons or their representatives only.
See section 2 for further details. - [Storage]:

7.3. Specific end use(s)
No data available.

8. Exposure controls and personal protection

8.1. Control parameters
There are no ingredients in this product which are classified as hazardous, and/or no hazardous ingredients above the GHS cut off percentage.

8.2. Exposure controls

<table>
<thead>
<tr>
<th></th>
<th>Not Applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory</td>
<td></td>
</tr>
<tr>
<td>Eyes</td>
<td></td>
</tr>
<tr>
<td>Skin</td>
<td></td>
</tr>
</tbody>
</table>
| Engineering Controls | Provide adequate ventilation. Where reasonably practicable this should be achieved by the use of local exhaust ventilation and good general extraction. If these are not sufficient to maintain concentrations of particulates and any vapor below occupational exposure limits suitable respiratory protection must be worn.

<table>
<thead>
<tr>
<th>Other Work Practices</th>
<th>Use good personal hygiene practices. Wash hands before eating, drinking, smoking or</th>
</tr>
</thead>
</table>
using toilet. Promptly remove soiled clothing and wash thoroughly before reuse.
See section 2 for further details. - [Prevention]

9. Physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Liquid</td>
</tr>
<tr>
<td>Odor</td>
<td>None</td>
</tr>
<tr>
<td>Odor threshold</td>
<td>Not Measured</td>
</tr>
<tr>
<td>pH</td>
<td>6.5-7.5</td>
</tr>
<tr>
<td>Melting point / freezing point</td>
<td>Not Measured</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>Not Measured</td>
</tr>
<tr>
<td>Flash Point</td>
<td>Not Measured</td>
</tr>
<tr>
<td>Evaporation rate (Ether = 1)</td>
<td>Not Measured</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Upper/lower flammability or explosive limits</td>
<td>Lower Explosive Limit: Not Measured</td>
</tr>
<tr>
<td></td>
<td>Upper Explosive Limit: Not Measured</td>
</tr>
<tr>
<td>Vapor pressure (Pa)</td>
<td>Not Measured</td>
</tr>
<tr>
<td>Vapor Density</td>
<td>Not Measured</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>Not Measured</td>
</tr>
<tr>
<td>Solubility in Water</td>
<td>Readily Soluble</td>
</tr>
<tr>
<td>Partition coefficient n-octanol/water (Log Kow)</td>
<td>Not Measured</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>Not Measured</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>Not Measured</td>
</tr>
<tr>
<td>Viscosity (cSt)</td>
<td>Not Measured</td>
</tr>
</tbody>
</table>

9.2. Other information
No other relevant information.

10. Stability and reactivity

10.1. Reactivity
Hazardous Polymerization will not occur.

10.2. Chemical stability
Stable under normal circumstances.

10.3. Possibility of hazardous reactions
No data available.

10.4. Conditions to avoid
Storage and transportation temperatures should not fall below 2C and not exceed 8C.

10.5. Incompatible materials
No data available.

10.6. Hazardous decomposition products
No hazardous decomposition data available.
11. Toxicological information

Acute toxicity

All product components are considered to be non-hazardous. The product is intended for local application on wound surface only, therefore no oral, dermal or inhalation toxicity studies have been performed.

Toxicity studies were performed with Beriplast

Single dose toxicity studies:
Acute toxicity studies were performed in rodents (mice, rats) with single i.p. and s.c. injection. In the i.p. and s.c. studies mice and rats were administered with a dose up to 30 mL/kg. In another study mice, rats and rabbits were administered with 0.1 mL/animal (mice and rats) or 0.2 mL/animal (rabbits) topical on skin wound. No relevant toxic findings were observed in these studies.

Local tolerance:
Rabbits were injected with 0.5 mL/animal i.m. or s.c.. The substance was regarded as local tolerable after s.c. and i.m. injection.

Repeated dose toxicity:
Rats were administered doses up to 10 mL/kg intraperitoneal over one week daily (7 doses in total) as well as over five weeks (12 doses in total). The substance was well tolerated.
There are no ingredients in this product which are classified as hazardous, and/or no hazardous ingredients above the GHS cut off percentage.

Note: When no route specific LD50 data is available for an acute toxin, the converted acute toxicity point estimate was used in the calculation of the product's ATE (Acute Toxicity Estimate).

<table>
<thead>
<tr>
<th>Classification</th>
<th>Category</th>
<th>Hazard Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity (oral)</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Acute toxicity (dermal)</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Acute toxicity (inhalation)</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Skin corrosion/irritation</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Serious eye damage/irritation</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Respiratory sensitization</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Skin sensitization</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Germ cell mutagenicity</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Reproductive toxicity</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>STOT-single exposure</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>STOT-repeated exposure</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Aspiration hazard</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>
12. Ecological information

12.1. Toxicity
No additional information provided for this product. See Section 3 for chemical specific data.
Vial 1 and 2 and 3: The nature as proteins do not provide any risk for the environment (water, soil, air).

Vial 4: The solution of 0.6% Calcium chloride in water does not provide risk for the environment. It can increase the hardness of water. A harmful effect of aquatic organisms is only to be expected in high concentration.

Aquatic Ecotoxicity
There are no ingredients in this product which are classified as hazardous, and/or no hazardous ingredients above the GHS cut off percentage.

12.2. Persistence and degradability
There is no data available on the preparation itself.

12.3. Bioaccumulative potential
Not Measured

12.4. Mobility in soil
No data available.

12.5. Results of PBT and vPvB assessment
This product contains no PBT/vPvB chemicals.

12.6. Other adverse effects
No data available.

13. Disposal considerations

13.1. Waste treatment methods
Observe all federal, state and local regulations when disposing of this substance.

14. Transport information

14.1. UN number
DOT (Domestic Surface Transportation) Not Applicable
IMO / IMDG (Ocean Transportation) Not Regulated
ICAO/IATA Not Regulated

14.2. UN proper shipping name
Not Regulated
Not Regulated
Not Regulated

14.3. Transport hazard class(es)
DOT Hazard Class: Not Applicable
IMDG: Not Applicable
Air class: Not Applicable

14.4. Packing group
DOT Hazard Class: Not Applicable
IMDG: Not Applicable

14.5. Environmental hazards
IMDG Marine Pollutant: No

14.6. Special precautions for user
15. Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU Legislation


National Legislation
None noted.

16. Other information

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The full text of the phrases appearing in section 3 is:
Not Applicable

This is the first version in the GHS SDS format. Listings of changes from previous versions in other formats are not applicable.

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