1. Identification

1.1. Product identifier
Product Identity	MonoFIX®-VF
Alternate Names	Human Coagulation Factor IX, powder for injection
32500192 (Aus), 32600194 (Aus), 32500292 (NZ), 32500492
(Singapore), 32500792 (Malaysia), 32500392 (HK), 32501892 (Taiwan)

1.2. Relevant identified uses of the substance or mixture and uses advised against
Intended use	For the treatment of haemorrhages, for use in surgery, and as prophylaxis
in patients with haemophilia B.
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

Supplier Name	CSL Behring (Australia) Pty Ltd (ABN 48 160 734 761).
189-209 Camp Road, Broadmeadows, Victoria 3047,
Australia

Emergency
24 hour Emergency Telephone No.	1800 642 865 (24hr)
Customer Service	+6 03 9246 5200

2. Hazard(s) identification

2.1. Classification of the substance or mixture
No applicable GHS categories. Not hazardous according to criteria of Australian WHS Regulations

2.2. Label elements
Using the Toxicity Data listed in section 11 and 12 the product is labeled as follows.
No applicable GHS categories.

[Prevention]:
No GHS prevention statements

[Response]:
No GHS response statements

[Storage]:
No GHS storage statements

[Disposal]:
No GHS disposal statements

### 3. Composition/information on ingredients

This product contains the following substances that present a hazard within the meaning of the relevant State and Federal Hazardous Substances regulations.

<table>
<thead>
<tr>
<th>Ingredient/Chemical Designations</th>
<th>Weight %</th>
<th>GHS Classification</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heparin, sodium salt</td>
<td>10 - 25</td>
<td>Not Classified</td>
<td>[1]</td>
</tr>
<tr>
<td>CAS Number: 0009041-08-1</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

In accordance with paragraph (i) of §1910.1200, the specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret.

[1] Substance classified with a health or environmental hazard.


*The full texts of the phrases are shown in Section 16.

Non-Hazardous Ingredients:
- Factor IX (1000IU)
- Human Plasma Proteins (less than or equal to 40mg)
- Antithrombin III (25IU)
- Heparin (100-280IU)
- Other non-hazardous ingredients (172mg)

### 4. First aid measures

#### 4.1. Description of first aid measures

**General**
In all cases of doubt, or when symptoms persist, seek medical attention.
Never give anything by mouth to an unconscious person.

**Inhalation**
Remove to fresh air.

**Eyes**
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**
Wash out mouth thoroughly with water, if irritation or discomfort persists seek medical attention.

#### 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
Non-Combustible. Not considered a significant fire risk.
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
Minor Spills: Soak up spills with absorbent material i.e. paper towels or vermiculite. Place spilled material in clean, dry, sealed container for disposal. Decontaminate area with 1% sodium hypochlorite in water.

Major Spills: Contain and absorb spills using earth, sand or inert absorbent. Prevent material entering open drains and waterways. Collect residues and seal in labelled drums for disposal. Decontaminate area with 1% sodium hypochlorite in water. Take care to avoid excessive dust during clean up. If dust is present wear a minimum P1 filter grade dust mask.

7. Handling and storage

7.1. Precautions for safe handling
Limit all unnecessary personal contact. Always wash hands with soap and water after handling.

7.2. Conditions for safe storage, including any incompatibilities
Handle containers carefully to prevent damage and spillage. Store at 2°C to 8°C (Refrigerate. Do not freeze). Protect from light. Incompatible materials: No data available.

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

8. Exposure controls and personal protection

8.1. Control parameters
Exposure
8.2. Exposure controls

**Respiratory**
If dust is present wear a minimum P1 filter grade dust mask.

**Eyes**
Protective safety glasses recommended

**Skin**
Protective gloves (e.g. latex or nitrile) recommended.

**Engineering Controls**
None under normal conditions

**Other Work Practices**
The local concentration of material, quantity and conditions of use determine the type of personal protective equipment required. For further information, consult your Occupational Health and Safety Adviser. Use good personal hygiene practices. Wash hands before eating, drinking, smoking or using toilet. Promptly remove soiled clothing and wash thoroughly before reuse.

9. Physical and chemical properties

**Appearance**
White Solid

**Odor**
Slight

**Odor threshold**
Not Measured

**pH**
6.7

**Melting point / freezing point**
Not Measured

**Initial boiling point and boiling range**
Not Measured

**Flash Point**
Not Measured

**Evaporation rate (Ether = 1)**
Not Measured

**Flammability (solid, gas)**
Not Applicable

**Upper/lower flammability or explosive limits**

<table>
<thead>
<tr>
<th>Source</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>OSHA</td>
<td>No Established Limit</td>
</tr>
<tr>
<td>ACGIH</td>
<td>No Established Limit</td>
</tr>
<tr>
<td>NIOSH</td>
<td>No Established Limit</td>
</tr>
<tr>
<td>Supplier</td>
<td>No Established Limit</td>
</tr>
</tbody>
</table>

**Carcinogen Data**

<table>
<thead>
<tr>
<th>CAS No.</th>
<th>Ingredient</th>
<th>Source</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>0009041-08-1</td>
<td>Heparin, sodium salt</td>
<td>OSHA</td>
<td>Select Carcinogen: No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NTP</td>
<td>Known: No; Suspected: No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>IARC</td>
<td>Group 1: No; Group 2a: No; Group 2b: No; Group 3: No; Group 4: No;</td>
</tr>
</tbody>
</table>
Partition coefficient n-octanol/water (Log Kow) Not Measured
Auto-ignition temperature Not Measured
Decomposition temperature Not Measured
Viscosity (cSt) Not Measured

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
No data available.

10.5. Incompatible materials
No data available.

10.6. Hazardous decomposition products
No hazardous decomposition data available.

11. Toxicological information

Acute toxicity

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Oral LD50, mg/kg</th>
<th>Skin LD50, mg/kg</th>
<th>Inhalation Vapor LC50, mg/L/4hr</th>
<th>Inhalation Dust/Mist LC50, mg/L/4hr</th>
<th>Inhalation Gas LC50, ppm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heparin, sodium salt - (9041-08-1)</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
</tr>
</tbody>
</table>

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).
12. Ecological information

12.1. Toxicity
No additional information provided for this product. See Section 3 for chemical specific data.

Aquatic Ecotoxicity

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>96 hr LC50 fish, mg/l</th>
<th>48 hr EC50 crustacea, mg/l</th>
<th>ErC50 algae, mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heparin, sodium salt - (9041-08-1)</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>DOT (Domestic Surface Transportation)</th>
<th>IMO / IMDG (Ocean Transportation)</th>
<th>ICAO/IATA</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
14.1. UN number Not Applicable
14.2. UN proper shipping name Not Regulated
14.3. Transport hazard class(es) DOT Hazard Class: Not Applicable
   IMDG: Not Applicable
   Sub Class: Not Applicable
   Air Class: Not Applicable
14.4. Packing group Not Applicable
14.5. Environmental hazards IMDG Marine Pollutant: No
14.6. Special precautions for user No further information

15. Regulatory information

Regulatory Overview Poisons Schedule Number: Unscheduled

16. Other information

The information and recommendations contained herein are based upon data believed to be correct. However, no guarantee or warranty of any kind, expressed or implied, is made with respect to the information contained herein. We accept no responsibility and disclaim all liability for any harmful effects which may be caused by exposure to our products. Customers/users of this product must comply with all applicable health and safety laws, regulations, and orders.

The full text of the phrases appearing in section 3 is:

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

The information contained herein is based upon data considered true and accurate. CSL Behring makes no warranties, express or implied, as to the adequacy of the information contained herein. This information is offered solely for the user's consideration, investigation, and verification. Report to the manufacturer any allegations of health effects resulting from handling or accidental contact with this material.

End of Document