

IMPORTANT NOTICE: This Safety Data Sheet (SDS) is prepared by CSL Behring in accordance with Safe Work Australia National Code of Practice for the Preparation of Safety Data Sheets (February 2016). The information contained herein must not be altered or deleted. Additional information may be appended to the SDS, but it must be marked clearly to indicate that it is not part of the original.

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 (Australia) Pty Ltd (ABN 48 160 734 761)
189-209 Camp Road, Broadmeadows, Victoria 3047, Australia

Telephone
+61 03 9246 5200

Emergency

24 hour Emergency Telephone No. 1800 642 865 (24hr)

2. Hazard(s) identification

Not classified as hazardous according to the WHS Regulations

All blood products should be treated as potentially infectious. No known test methods can offer assurance that products derived from human blood will not transmit infectious agents.

GHS Classification(s)	None Allocated
Signal Word	No signal word
Pictogram(s)	No Pictogram(s)
Hazard Statement(s)	None Allocated
Prevention statement(s)	None Allocated
Response	None Allocated
Storage	None Allocated
Disposal	None Allocated

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.

Ingredient/Chemical Designations	CAS Number	Composition
Factor IX	-	1000IU
Human Plasma Proteins	-	≤ 40mg
Antithrombin III	-	25IU
Heparin, sodium salt	9041-08-1	10 – 25 %
Other non-hazardous ingredients	-	Up to 100%

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

CAS No.	Ingredient	Source	Value
0009041-08-1	Heparin, sodium salt	OSHA	No Established Limit
		ACGIH	No Established Limit
		NIOSH	No Established Limit
		Supplier	No Established Limit

Carcinogen Data

CAS No.	Ingredient	Source	Value
0009041-08-1	Heparin, sodium salt	OSHA	Select Carcinogen: No
		NTP	Known: No; Suspected: No
		IARC	Group 1: No; Group 2a: No; Group 2b: No; Group 3: No; Group 4: No;

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	Lower Explosive Limit: Not Measured Upper Explosive Limit: Not Measured
Vapor pressure (Pa)	Not Measured
Vapor Density	Not Measured
Specific Gravity	Not Measured
Solubility in Water	Complete
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

Ingredient	Oral LD50, mg/kg	Skin LD50, mg/kg	Inhalation Vapor LC50, mg/L/4hr	Inhalation Dust/Mist LC50, mg/L/4hr	Inhalation Gas LC50, ppm
Heparin, sodium salt - (9041-08-1)	No data available	No data available	No data available	No data available	No data available

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).

Classification	Category	Hazard Description
Acute toxicity (oral)	---	Not Applicable
Acute toxicity (dermal)	---	Not Applicable
Acute toxicity (inhalation)	---	Not Applicable
Skin corrosion/irritation	---	Not Applicable
Serious eye damage/irritation	---	Not Applicable
Respiratory sensitization	---	Not Applicable
Skin sensitization	---	Not Applicable
Germ cell mutagenicity	---	Not Applicable
Carcinogenicity	---	Not Applicable
Reproductive toxicity	---	Not Applicable
STOT-single exposure	---	Not Applicable

STOT-repeated exposure	---	Not Applicable
Aspiration hazard	---	Not Applicable

12. Ecological information

12.1. Toxicity

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

Aquatic Ecotoxicity

Ingredient	96 hr LC50 fish, mg/l	48 hr EC50 crustacea, mg/l	ErC50 algae, mg/l
Heparin, sodium salt - (9041-08-1)	Not Available	Not Available	Not Available

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

Product:

In accordance with state land and waste management authority.
Incineration in controlled furnaces.

Packaging:

Must be disposed of in compliance with country-specific regulations.

14. Transport information

Not classified as a dangerous good by the criteria of the ADG Code

14.1. UN number	Not Applicable
14.2. UN proper shipping name	Not Regulated
14.3. Transport hazard class(es)	Not Applicable
14.4. Packing group	Not Applicable
14.5. Environmental hazards	Marine pollutant: No
14.6. Special precautions for user	No further information

15. Regulatory information

Poisons Schedule Number (SUSMP) Schedule 4 (S4) – Prescription only medicine

16. Other information

Last Revised 04/04/2017

Reason for Revision Update Company details
Update to GHS requirements

Abbreviations

SWA	Safe Work Australia
GHS	Globally Harmonised System
WHS	Work, Health and Safety
ACGIH	American Conference of Governmental Industrial Hygienists
ADG Code	Australian Dangerous Goods Code
UN Number	United Nations Number
DG Class	Dangerous Goods Class
CAS Number	Chemical Abstract Service Number

Contact Point

Company Contact: 1800 642 865 (24hr)

Australian Poisons Information Centre, 24 hour service: 13 11 26

Australian Police, Fire Brigade or Ambulance: 000

New Zealand Poisons Information Centre, 24 hour service: 0800 764 766

New Zealand Police, Fire Brigade or Ambulance: 111

Whilst the information contained in this document is based on data which, to the best of our knowledge, was accurate and reliable at the time of preparation, no responsibility can be accepted by us for errors and omissions. Users are advised to make their own determination as to the suitability of this information in relation to their particular purposes and specific circumstances. Since the information contained in this document may be applied under conditions beyond our control, we can accept no responsibility for any loss or damage by any person acting or refraining from action as a result of this information.

