

**MATERIAL SAFETY DATA SHEET**

Last revision : 1, issued: 20/03/2014

**ENGLISH****SECTION 1: PRODUCT & COMPANY IDENTIFICATION****1.1. Product identifier**

Name	Product number
RECOMBINANT HIRUDIN	RE120A
	RE120B

**1.2. Relevant identified uses of the substance or mixture and uses advised against**

The product must be used according strictly to the instructions of package insert, and for the indicated purpose.

**1.3. Details of the manufacturer and supplier of the safety data sheet**

Manufacturer: HYPHEN BioMed  
155 rue d'Eragny  
95000 Neuville sur Oise (France)  
Tel: 33.1.34.40.65.10  
Fax: 33.1.34.48.72.36  
E-mail address: [info@hyphen-biomed.com](mailto:info@hyphen-biomed.com)

**1.4. Emergency telephone number**

Tel: 33.1.34.40.65.10

**SECTION 2: HEALTH HAZARDS IDENTIFICATION****2.1. Classification of the substance or mixture****Classification information**

This product does not meet the classification and labeling criteria given in the Dangerous Preparations Directive 1999/45/EC.

**2.2. Label elements**

Biohazard

**2.3. Other hazards****PBT assessment**

No data available.

**vPvB assessment**

No data available.

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**SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS****3.1. Substances**

Not applicable, the product is not a substance

**3.2. Mixtures****Hazardous ingredients**

This product does not contain substances to be mentioned according to EU Regulation No 1272/2008 or UE 67/548/CEE and 1999/45/CE.

**3.3. Other information**

Do not inject or ingest.

Serum and purified animals factors were prepared from animal's plasma; which was tested for the absence of infectious agents. Because no known test method can assure complete absence of pathogens this product should be handled with appropriate precautions.

**SECTION 4: FIRST AID MEASURES****4.1. Description of first aid measures****General information**

In case of persisting adverse effects, consult a physician. Remove contaminated clothing and shoes immediately, and launder thoroughly before reusing.

**After inhalation**

Removed affected person from the immediate area. Ensure supply of fresh air.

**After skin contact**

Wash off immediately with soap and water.

**After eye contact**

Separate eyelids; wash the eyes thoroughly with water (15 min).

**After ingestion**

Summon a doctor immediately. Do not induce vomiting. Never give anything by mouth to an unconscious person.

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

No data available.

**4.3. Indication of any immediate medical attention and special treatment needed**

No data available.

**SECTION 5: FIRE AND EXPLOSION HAZARDS DATA****5.1. Extinguishing media****Suitable extinguishing media**

Product itself is non-combustible; adapt fire extinguishing measures to surrounding areas

**Unsuitable extinguishing media**

No data available.

**5.2. Special hazard arising from the substance or mixture**

In the event of fire, the following can be released: Carbon dioxide (CO<sub>2</sub>); Carbon monoxide (CO)

**5.3. Advice for firefighters**

Use self-contained breathing apparatus. Wear protective clothing.

**SECTION 6: SPILL, LEAK AND DISPOSAL PROCEDURES****6.1. Personal protections, protective equipment and emergency procedures****For non-emergency personnel**

Refer to protective measures listed in section 7 and 8. Avoid contact with skin, eyes and clothing.

**For emergency responder**

No data available. Personal protective equipment (PPE) – see section 8.

**6.2. Environmental precautions**

Do not discharge into the drains/surface water/groundwater. Do not discharge into the subsoil/soil.

**6.3. Methods and material for containment and cleaning up**

Take up with absorbent material. When picked up, treat material as prescribed under heading “Disposal considerations”.

**SECTION 7: CAUTIONS TO BE TAKEN IN HANDLING AND STORAGE****7.1. Precautions for safe handling****Advice on safe handling**

Product inherent handling risks must be minimised taking the appropriate measures for protection and preventive actions. The working process should be designed to rule out the release of hazardous substances or skin contact as far it is possible by state of the art.

**General protective and hygiene measures**

Do not eat, drink or smoke during work time. Keep away from food, drink and animal feeding stuffs. Wash hands and skin before breaks and after work. Do not inhale vapours. Avoid contact with eyes and skin. Remove soiled or soaked clothing immediately.

**Advice on protection against fire and explosion**

No special measures necessary.

**7.2. Conditions for safe storage, including any incompatibilities****Technical measures and storage conditions**

Keep container tightly closed. Store in refrigerator.

**Recommended storage temperature**

Value: 2 - 8°C

**Requirements for storage rooms and vessels**

Containers which are opened must be carefully closed and kept upright to prevent leakage.

**SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION****8.1. Control parameters**

No parameters available for monitoring.

**8.2. Exposure controls****Appropriate engineering controls**

No data available.

**Personal protective equipment****Respiratory protection**

If workplace exposure limits are exceeded, a respiration protection approved for this particular job must be worn. In case of aerosol and mist formation, take appropriate measures for breathing protection in the event workplace threshold values are not specified.

**Eye / face protection**

Safety glasses (EN 166)

**Hand protection**

In case of intensive contact, wear protective gloves (EN 374). Before use, the protective gloves should be tested in any case for its specific work-station suitability (i.e. mechanical resistance, product compatibility and antistatic properties). Adhere to the

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manufacturer's instructions and information relating to the use, storage, care and replacement of protective gloves. Protective gloves shall be replaced immediately when physically damaged or worn. Design operations thus to avoid permanent use of protective gloves.

**Other**

Normal chemical work clothing.

**Environmental exposure controls**

No data available.

**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

**9.1. Information on basic physical and chemical properties**

Property	Recombinant HIRUDIN
Appearance	Lyophilised powder
Odour	None
pH value	No data available.
Boiling point	No data available.
Melting point	No data available.
Decomposition point	No data available.
Flash point	No data available.
Auto-ignition temperature	No data available.
Oxidising properties	No data available.
Explosive properties	No data available.
Flammability	No data available.
Lower flammability or explosive limits	No data available.
Upper flammability or explosive limits	No data available.
Vapour pressure	No data available.
Vapour density	No data available.
Evaporation rate	No data available.
Relative density	No data available.
Solubility in water	No data available.
Solubility	No data available.
Partition coefficient: n-octano/water	No data available.
Viscosity	No data available.
Other information	No data available.

**SECTION 10: STABILITY AND REACTIVITY**

**10.1. Reactivity**

No data available.

**10.2. Chemical stability**

Stable.

**10.3. Possibility of hazardous reactions**

No data available.

**10.4. Conditions to avoid**

No data available.

**10.5. Incompatible materials**

None known.

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**10.6. Hazardous decomposition products**

Carbon monoxide, carbon dioxide, nitrogen oxide.

**SECTION 11: TOXICOLOGICAL INFORMATION**

**11.1. Information on toxicological effects**

Effects	Recombinant HIRUDIN
Acute oral toxicity	No data available.
Acute dermal toxicity	No data available.
Acute inhalational toxicity	No data available.
Skin corrosion/irritation	No data available.
Serious eye damage/irritation	No data available.
Respiratory or skin sensitisation	No data available.
Germ cell mutagenicity	No data available.
Reproduction toxicity	No data available.
Carcinogenicity	No data available.
Stot-single exposure	No data available.
Stot-repeated exposure	No data available.
Aspiration hazard	No data available.

**SECTION 12: ECOLOGICAL INFORMATION**

**12.1. Toxicity**

Toxicity	Recombinant HIRUDIN
Fish toxicity	No data available.
Daphnia toxicity	No data available.
Algae toxicity	No data available.
Bacteria toxicity	No data available.

**12.2. Persistence and degradability**

No data available.

**12.3. Bio-accumulative potential**

No data available.

**12.4. Mobility in soil**

No data available.

**12.5. Results of PBT and vPvB assessment**

Assessment	Recombinant HIRUDIN
PBT assessment	No data available.
vPvB assessment	No data available.

**12.6. Other adverse effects**

No data available.

**12.7. Other information**

Other information
Do not discharge product unmonitored into the environment.

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**SECTION 13: WASTE DISPOSAL CONSIDERATIONS****13.1. Waste treatment methods****Product**

Allocation of a waste code number, according to the European waste catalogue, should be carried out in agreement with the regional waste disposal company.

**Packaging**

Residuals must be removed from packaging and when emptied completely disposed of in accordance with the regulations for waste removal. Incompletely emptied packaging must be disposed of in the form of disposal specified by the regional disposer.

**SECTION 14: TRANSPORT AND STORAGE INFORMATION****14.1. transport ADR/RID/AND**

The product is not subject to ADR/RID/ADN regulations.

**14.2. Transport IMDG**

The product is not subject to IMDG regulations.

**14.3. Transport ICAO-TI / IATA**

The product is not subject to ICAO-TI / IATA regulations.

**14.4. Other information**

No data available.

**14.5. Environmental hazards**

Information on environmental hazards, if relevant, pls. See 14.1 - 14.3.

**14.6. Special precautions for user**

No data available.

**14.7. Transport in bulk according to annex II of MARPOL 73/78 and the IBC Code**

Not relevant

**SECTION 15: REGULATORY INFORMATION****15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****EU regulations**

This MSDS file is comply to the requirements described on the Regulation (EC) No 1907/2006 (REACH)

**15.2. Chemical safety assessment**

No data available.

**SECTION 16: OTHER INFORMATION**

The information reported on this MSDS is believed to be accurate and represents the best information available to us. However, we make no warranty of merchantability or any other warranty, expressed or implied, with respect to such information, and we assure no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes. HYPHEN BioMed and its appointed agents/distributors or OEM contractors shall not be held liable for any damage resulting from or from contact with the products included in the kit.