

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

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.

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 animal 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

Remove 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 (CO₂); 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.