

**Section 11:            Alternatives to the Proposed Action**

The Tier 0 approach is taken for this application and the information for format item 11 is excluded.

**Section 12:            List of Preparers**

In addition to the list of preparers provided in the complete EA of August 23, 1994, the following person is added to the list. Attachment II provides the CV of the preparer of this Tier 0 Environmental Assessment.

William Studt (Ph.D. Synthetic Organic Chemistry)  
Process Chemistry  
Process Analysis and Documentation  
Rhône-Poulenc Rorer  
Collegeville, PA

**Section 13:            Certification**

Attachment III contains the certification as to the veracity of this document.

**Section 14:            References**

Information for format item 14 does not differ from the complete EA provided August 23, 1994.

**Section 15:            Appendices**

Information for format item 15 differs from the complete EA provided August 23, 1994 only in the addition of the CV of the preparer of this Tier 0 (see Attachment II) and a certification as to the veracity of this document (see Attachment III).

Attachment I: Enoxaparin Drug Substance Information

Attachment II: CV of the Preparer

Attachment III: Certification

# Attachment I

## Enoxaparin Drug Substance

### Physical and Chemical Characteristics

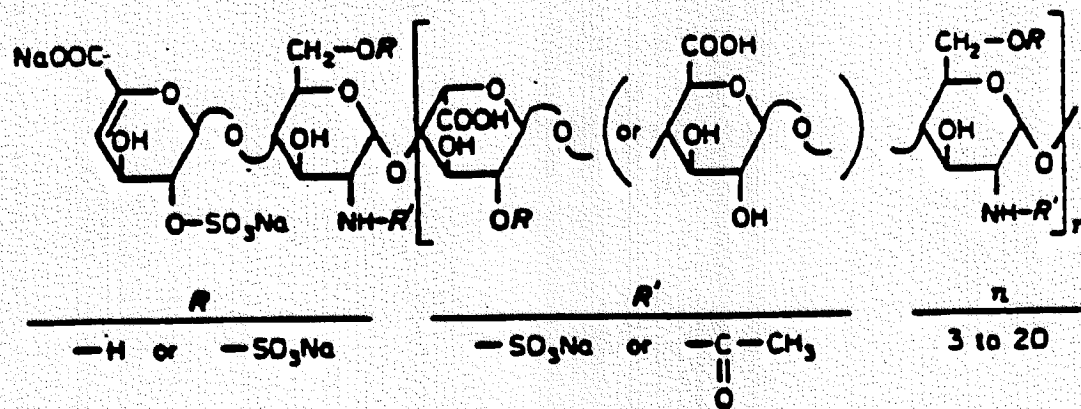
#### MSDS's

## Appendix II

### Enoxaparin Drug Substance Physical and Chemical Characteristics

<b>Name:</b>	Enoxaparin
<b>CAS Reg. No.:</b>	Not available
<b>Molecular Weight:</b>	Mean - 4500    Range - 3500 to 5550
<b>Physical Description:</b>	White to slightly white-yellowish, odorless powder
<b>Additives:</b>	None
<b>Residuals:</b>	Benzyl alcohol and benzethonium, Residual Solvents: Methanol/Methylene Chloride

**Structural Formula:**



[Pharmaceutical information]

APPEARS THIS WAY ON ORIGINAL

Translated from French by the Ralph McElroy Company, Custom Division  
P.O. Box 4828, Austin, TX 78765 USA

Code: 681-17354

Date of issue: June 17, 1992

Ref.: 074488

**1. Identification Enoxaparin****1.1 Manufacturer**

Rhône-Poulenc Rorer Active Principles  
Production Center of Vitry-Villeneuve-La-Garenne  
B.P. 35 94403 Vitry Sur-Seine Cedex France

**1.2 Department to be contacted Safety**

Telephone (33-1) 46 85 91 91

**2. Composition/Information on the components**

RN OA8: 0041-08-1

EINECS: 232-801-7 for heparin

Substances presenting a danger : Enoxaparin

Impurities presenting a danger : None

Other information : low molecular weight  
heparin sodium, molecular  
weight approximately 4500

**3. Identification of the dangers**

None

**4. First aid**

In case of contact with the eyes : wash immediately  
with a large amount

In case of persistent irritation:

of water for at least 15 minutes.

consult an ophthalmologist.

In case of ingestion:

consult a doctor and show him the package, or the label.

## 5. Fire-fighting measures

5.1 Recommended extinguishing method:

sprayed water, foam, powder.

5.2 Contraindicated extinguishing method:

concentrated jet of water.

5.3 Particular dangers of fire or explosion:

emission of nitrogen and sodium oxides.

5.4 Particular fire-fighting protective measures: wearing of self-contained mask recommended.

## 6. Measure to be taken in case of accidental dispersion

6.1 Individual precautions:

dust mask, gloves, glasses, protective clothing.

6.2 Precautions for the protection of the environment:

collect the product with a scoop to the maximum, then wash with a large amount of water.

- 6.3 Methods of cleaning: rinsing with a large amount of water.
7. Handling and storage
- 7.1 Handling: under a hood
  - 7.2 Storage: in sealed packages
8. Explosion control/individual protection
- 8.1 Respiratory protection: dust mask
  - 8.2 Protection of the hands: gloves
  - 8.3 Protection of the eyes: glasses
  - 8.4 Protection of the skin: work clothes
  - 8.5 Particular measure of hygiene: shower after working
9. Physical and chemical properties
- 9.1 Appearance: white to yellowish white powder
  - 9.2 Odor: practically odorless
  - 9.3 pH: 6 to 7.5 in 20 g/L aqueous solution
  - 9.4 Boiling point: not applicable
  - 9.5 Melting point: undetermined
  - 9.6 Flash point: not applicable
  - 9.7 Flammability (solid): undetermined
  - 9.8 Spontaneous ignition capability: undetermined
  - 9.9 Dangers of explosion: yes, in case of the dust
  - 9.10 Oxidant properties
  - 9.11 Vapor pressure: not applicable
  - 9.12 Apparent density: 0.55
  - 9.13 Solubility: water solubility: 50 g/liter

Alcohol, acetone, benzene, chloroform: practically insoluble

9.14 n-octanol/water partition coefficient: undetermined

10. Stability and reactivity

10.1 Conditions to be avoided: accidental mixtures

10.2 Materials to be avoided: strong oxidizing agents

10.3 Dangerous products of decomposition: nitrogen and sodium oxides

11. Toxicological information

LD50, orally in mice: higher than 5000 mg/kg (RTECS up-dated the 1st trimester 1992)

12. Ecological information: undetermined

13. Considerations relating to elimination

Product: incineration in an authorized installation.

Contaminated packages: incineration of the packages which have been in direct contact with the product, in an authorized installation.

14. Information relating to transport

Regulations for transporting dangerous materials do not apply to the products.

15. Regulatory information

European voluntary labeling: not applicable.



Particular conditions relating to the dust: limit value of exposure (LVE) 1 mg/m<sup>3</sup> of air, for 8 hours of exposure (determined from the therapeutic dose).

Note: Comply with any other national conditions which are applicable.

#### 16. Other information

16.1 Recommendations relating to training: notify concerning the precautions to be taken and equip the personnel.

16.2 Uses: pharmaceutical uses, antithrombotic.

The drug obtained from this active material is Lovenox (Pharmuka Laboratory).

16.3 Source of the principal data used in the card: Rhône-Poulenc Rorer documentation, Merck Index 11th edition, Dangerous Properties of Industrial Materials 7th edition.

#### Important

This card completes the technical information for use, but does not replace it. The information it contains is based on the state of our knowledge relating to the product in consideration on the date when it is issued.

In no case does this information relieve the user of the product from the responsibility of referring to the official texts in force in order to know his obligations in the matter of hygiene, safety, and environment on this subject. The attention of the users is also drawn to the possible risks that are run when a product is used for uses other than those for which it is designed and provided for by this card.

This information is given in good faith and involves no guarantee or obligation on our part for any reason whatsoever.

BEST POSSIBLE

APPEARS THIS WAY ON ORIGINAL