

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

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2. Composition/Information on the components

RN OAS: 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

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4. First aid

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

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In case of persistent irritation:

of water for at least 15 minutes.

In case of ingestion:

consult an ophthalmologist.
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.

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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

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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.

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Particular conditions relating to the dust: limit value of exposure (LVE) 1 mg/m³ 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

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.

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

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1. IDENTIFICATION

ENOXAPARINE

1.1 Fabricant

RHONE-POULENC ROBER PRINCIPES ACTIFS
Centre de Production de VITRY-VILLENEUVE-LA-GARENNE
B.P.35 94403 VITRY SUR-SEINE Cedex FRANCE

1.2 Service à contacter

Sécurité

Tél : (33-1) 45 65 81 81

2. COMPOSITION / INFORMATIONS SUR LES COMPOSANTS

Rn CAS : 0041-08-1

EINECS : 232-601-7 pour l'héparine

Substance apportant un danger
Impuretés présentant un danger
Autres données

: Enoxaparine
: néant
: Héparine sodique de faible poids moléculaire
: poids moléculaire 4500 environ

3. IDENTIFICATION DES DANGERS

NEANT

4. PREMIERS SECOURS

En cas de contact avec les yeux

: laver immédiatement et abondamment avec de l'eau pendant au moins 15 minutes.

En cas d'irritation persistante
En cas d'ingestion

: consulter un ophtalmologiste.
: consulter un médecin et lui montrer l'emballage ou l'étiquette.

5. MESURES DE LUTTE CONTRE L'INCENDIE

5.1 Moyens d'extinction recommandés
5.2 contre-indiqués

: eau pulvérisée, mousses, poudre.

: jet d'eau-bâton

5.3 Dangers particuliers d'incendie ou d'explosion

: émission d'oxydes d'azote et de sodium

5.4 Mesures particulières de protection dans la lutte contre l'incendie

: port de masque autonome recommandé.

6. MESURES A PRENDRE EN CAS DE DISPERSION ACCIDENTELLE

6.1 Précautions individuelles

: masque à poussières, gants, lunettes, vêtements de protection.

6.2 Précautions pour la protection de l'environnement

: ramasser le produit à la pelle au maximum, puis laver à grande eau.

6.3 Méthodes de nettoyage

: rinçage à grande eau.

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7. MANIPULATION ET STOCKAGE

- 7.1 Manipulation : avis notiv
 7.2 Stockage : en emballages étanches

8. CONTROLE DE L'EXPOSITION / PROTECTION INDIVIDUELLE

- 8.1 Protection respiratoire : masque à poussières
 8.2 Protection des mains : gants
 8.3 Protection des yeux : lunettes
 8.4 Protection de la peau : vêtements de travail
 8.5 Mesure d'hygiène personnelle : douche après le travail.

9. PROPRIETES PHYSIQUES ET CHIMIQUES

- 9.1 Aspect : poudre blanche à blanc jaunâtre
 9.2 Odeur : pratiquement inodore
 9.3 pH : 6 à 7,5 en solution aqueuse à 20g/litre
 9.4 Point d'ébullition : non applicable
 9.5 Point de fusion : non déterminé
 9.6 Point d'éclair : non applicable
 9.7 Inflammabilité (solide) : non déterminée
 9.8 Auto-inflammabilité : oui pour les poussières
 9.9 Dangers d'explosion : non
 9.10 Propriétés comburantes : non applicable
 9.11 Pression de vapeur : 0,55
 9.12 Densité apparente : 50g/litre
 9.13 Solubilité: hydrosolubilité : pratiquement insoluble
 Alcool, Acétone, Benzène, Chloroforme : non déterminé
 9.14 Coefficient de partage n-octanol/eau

10. STABILITE ET REACTIVITE

- 10.1 Conditions à éviter : les mélanges instables
 10.2 Matières à éviter : les oxydants puissants
 10.3 Produits de décomposition dangereux : oxydes d'azote et de sodium

11. INFORMATIONS TOXICOLOGIQUES

- DL50 voie orale souris : supérieure à 5000 mg/kg (RTECS mis à jour 1er trimestre 92)

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12. INFORMATIONS ECOLOGIQUES

non déterminées

13. CONSIDERATIONS RELATIVES A L'ELIMINATION

Produit : incinération dans une installation autorisée.
 Emballages contaminés : incinération des emballages ayant été directement en contact avec le produit en installation autorisée.

14. INFORMATIONS RELATIVES AU TRANSPORT

Produit non concerné par les réglementations du transport des matières dangereuses.

15. INFORMATIONS REGLEMENTAIRES

Etiquetage volontaire européen : non concerné
 Dispositions particulières concernant les poussières : valeur limite d'exposition (VLE) 1 mg/m³ d'air, pour une exposition de 8 heures (détermination à partir de la dose thérapeutique).
 N.B. : Se conformer à toute autre disposition nationale applicable

16. AUTRES INFORMATIONS

16.1 Conseils relatifs à la formation : avertir des précautions à prendre et équiper le personnel concerné de moyens adéquats de protection individuelle
 16.2 Utilisations : usages pharmaceutiques, antithrombotiques
 Le médicament obtenu à partir de cette matière active est le Lovenox (laboratoire Pharmuka)
 16.3 Source des principales données utilisées dans la fiche : documentation Rhône-Poulenc Rorot, Microk Index 11ème édition
 Dangerous Properties of Industrial Materials 7ème édition

IMPORTANT

Cette fiche complète la notice technique d'utilisation mais ne la remplace pas. Les renseignements qu'elle contient sont basés sur l'état de nos connaissances relatives au produit concerné, à la date d'édition.
 En aucun cas ces renseignements ne dispensent l'utilisateur du produit de se reporter aux textes officiels en vigueur pour connaître les obligations qui lui incombent en matière d'hygiène, de sécurité et d'environnement en la matière. L'attention des utilisateurs est en outre attirée sur les risques éventuellement encourus lorsqu'un produit est utilisé à d'autres usages que ceux pour lequel il est conçu et prévu par cette fiche.
 Ces renseignements sont fournis de bonne foi et n'impliquent aucune garantie, ni aucun engagement de notre part pour quelque motif que ce soit.

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MATERIAL SAFETY DATA SHEET

MSDS Date: 8/17/92
Revision #1

Prepared by: Gayla J. McCluskey

1. PRODUCT AND COMPANY IDENTIFICATION

Lovenox® Injection

RHÔNE-POULENC RORER
500 Arcola Road, P.O. Box 1200
Collegeville, PA 19426-0107
Emergency Phone: (215) 454-8000

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2. COMPOSITION/INFORMATION ON INGREDIENTS

A sterile solution of enoxaparin in water. Enoxaparin is a depolymerized heparin obtained from porcine mucosa.

3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

No known hazards in handling product.

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Potential Health Hazards

EYE: No data

SKIN: No data. Some patients receiving this product by injection show local redness and swelling.

INGESTION: No data

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INHALATION: No data

CHRONIC EFFECTS: No long term studies have been performed to evaluate carcinogenic potential. Short term genetic toxicity tests were negative for chromosomal damage. No fertility or reproductive effects were observed in rats.

4. FIRST AID MEASURES

EYES: Flush with water. If irritation occurs, obtain medical attention.

SKIN: Wash with soap and water. If irritation occurs, obtain medical attention.

INGESTION: Rinse excess from mouth. Obtain medical attention.

INHALATION: Obtain medical attention.

NOTE TO PHYSICIANS: Additional details are available on the package insert or in the Physicians' Desk Reference.

5. FIRE FIGHTING MEASURES

FLAMMABLE PROPERTIES:

FLASH POINT: None Method: Not applicable

FLAMMABLE LIMITS:

Lower flammable limit: Not applicable

Upper flammable limit: Not applicable

AUTOIGNITION TEMPERATURE: None

HAZARDOUS COMBUSTION PRODUCTS: None

EXTINGUISHING MEDIA: Packaging material fires may be extinguished with water, carbon dioxide, halon or dry chemical.

FIREFIGHTING INSTRUCTIONS: Firefighting in confined spaces requires full protective gear and supplied air respiratory protection.

6. ACCIDENTAL RELEASE MEASURES

SMALL SPILL: Absorb on paper towels. Deposit in suitable container for disposal. Broken glass requires additional caution.

LARGE SPILL: Contain spill. Absorb on suitable medium and deposit in container for disposal. Mop area.

7. HANDLING AND STORAGE

HANDLING: Protect package from physical damage

STORAGE: Store at temperature below 25°C. Do not freeze.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

ENGINEERING CONTROLS: Manufacturing and packaging operations should be designed to offer no significant exposure to this material. Sterile operating conditions should prevent exposure.

RESPIRATORY PROTECTION: Once packaged, none required.

SKIN PROTECTION: Once packaged, none required. Protective gloves recommended for administration of product and spill clean up.

EYE PROTECTION: Once packaged, none required.

9. PHYSICAL AND CHEMICAL PROPERTIES

BOILING POINT: Approx. 212°F

MELTING POINT: N/A

VAPOR PRESSURE: As water

VAPOR DENSITY: As water

SOLUBILITY IN WATER: Soluble

SPECIFIC GRAVITY: 1-1.11

pH: 5.5-7.5

ODOR: No data

APPEARANCE: Clear colorless to pale yellow solution in 30ml syringe.

10. STABILITY AND REACTIVITY

CHEMICAL STABILITY: Product has a shelf life that is temperature dependent.

INCOMPATIBILITY: No data

HAZARDOUS DECOMPOSITION PRODUCTS: No data

HAZARDOUS POLYMERIZATION: Will not occur

11. TOXICOLOGICAL INFORMATION

Manufacturing and packaging employees should consult the MSDSs for the ingredients of this product. Product information is described on the package insert or in the Physicians' Desk Reference.

12. ECOLOGICAL INFORMATION

No data

13. DISPOSAL CONSIDERATIONS

Not a listed hazardous waste. Observe all Federal, State, and local regulations

14. TRANSPORT INFORMATION

Not a regulated material

15. REGULATORY INFORMATION

No additional data

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16. OTHER INFORMATION

Please report to the manufacturer any allegations of health effects resulting from handling or accidental contact with this material.

The information contained herein is based upon data considered true and accurate. Rhône-Poulenc Rorer 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.

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