

Safety Data Sheet in accordance with Regulation (EC) n°1907/2006	
Lovenox MDV Substance key: SXR114822 Version:3.0 (World) Revision Date: 19.04.2018	

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name: Lovenox MDV

Synonyms: Clexane MDV

REACH-No.:

A registration number is not available for this substance as the substance or its use are exempted from registration according to Article 2 REACH Regulation (EC) No 1907/2006, the annual tonnage does not require a registration or registration is envisaged for a later registration deadline.

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

Identified uses:
Drug product for medical use.

1.3. Details of the supplier of the safety data sheet

Sanofi-Aventis Deutschland GmbH
Brüningstrasse 50
65926 Frankfurt am Main
Telephone: +49 (0) 69 305- 0

Information provided by
HSE Germany
Telephone: +49 (0) 69 305-3963/-12590

Safety data sheet created by : HSE Germany Produktsicherheit (Produktsicherheit@Sanofi.com)

1.4. Emergency telephone number: +49 (0) 69 305-6418

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture:

CLP/GHS Classification (REGULATION (EC) No 1272/2008)

Not a dangerous substance according to GHS.

2.2. Label elements:

CLP/GHS-Labeling (REGULATION (EC) No 1272/2008)

Hazard warning labelling not compulsory

2.3. Other hazards:

Physical, chemical and toxicological hazards : Please read the Physicians Desk Reference for detailed pharmacological information.
Avoid contact with skin and eyes

SECTION 3: Composition/information on ingredients

Product Description : Contains: Enoxaparine sodium, Benzyl alcohol and Water.

3.2. Mixtures:

Hazardous substance name (CAS-No., EC-No., REACH-No.)	CLP/GHS Classification	Concentration
Benzyl alcohol (100-51-6, 202-859-9, 01-2119492630-38-XXXX (Merck, Acros, Solvadis))	Acute toxicity 4; H302 Acute toxicity 4; H332 Eye irritation 2; H319	(avg. 1,50 %)
Enoxaparine Sodium (679809-58-6, 696-630-4)	This substance is not classified as dangerous according to European Union legislation.	(avg. 10,00 %)

SECTION 4: First aid measures

4.1. Description of first aid measures:

General advice : Remove contaminated clothing immediately and dispose of safely.

If inhaled : When spray fog inhaled, seek medical aid immediately and show the physician the packing or the packing label.

In case of skin contact : In case of contact with skin wash off immediately with plenty of water.

In case of eye contact : In case of contact with eyes rinse thoroughly with plenty of water and seek medical advice

If swallowed : When swallowed seek medical aid immediately and show the physician the packaging or the label of the packaging.

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

Symptoms : No information available.

Hazards : No information available.

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

Treatment : Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media:

Suitable extinguishing media : Extinguishing measures to suit surroundings

5.2. Special hazards arising from the substance or mixture:

In case of combustion, evolution of dangerous gases possible.

5.3. Advice for firefighters:

- Special protective equipment : Use self-contained breathing apparatus.
- Further information : Fire residues and contaminated firefighting water must be disposed of in accordance with the local regulations.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures:

Use personal protective clothing.

6.2. Environmental precautions:

Do not allow to enter drains or waterways.

6.3. Methods and materials for containment and cleaning up:

- General advice : Pick up with absorbent material (eg sand, kieselgur, acid binder, universal binder, sawdust).
 Clean contaminated floors and objects thoroughly, observing environmental regulations
 When picked up, treat material as prescribed under heading "Disposal".

6.4. Reference to other sections:

Information regarding Safe handling, see chapter 7. Information regarding personal protective measures see, chapter 8.
 Information regarding Waste Disposal, see chapter 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling:

- Advice on safe handling (industrial scale) : Avoid formation of aerosols. Provide exhaust ventilation.
- Advice on protection against fire and explosion : Take precautionary measures against electrostatic loading.
 Observe the general rules of industrial fire protection

7.2. Conditions for safe storage, including any incompatibilities:

- Requirements for storage rooms and vessels : Keep only in the original container
- Further information on storage conditions : Keep container tightly closed and dry

7.3. Specific end use(s):

SECTION 8: Exposure controls/personal protection

8.1. Control parameters:

Ingredients with occupational exposure limits:

Hazardous substance name	: Enoxaparine Sodium
CAS-No.	: 679809-58-6
OEL-8h (Sanofi):	: 0,080 mg/m3
Remarks	: (approved)

Sanofi Hygiene Hazard Band Ingredients (Further information see chapter 16.):

Enoxaparine Sodium : OEB 3 (approved)

8.2. Exposure controls:

Personal protection equipment

(IMPORTANT: to be adapted following the workplace risk assessment.)

General protective measures : Avoid contact with eyes and skin.
A workplace risk assessment must be carried out in order to determine the correct engineering control measures and personal protective equipment.

Industrial workplace

Respiratory protection : Use respiratory protection in case of insufficient exhaust ventilation or prolonged exposure.
Multi-range filter ABEK/P3

Hand protection : In splash contact:
Nitrile rubber gloves.
Glove material : Camatril® (KCL)
Layer thickness : 0,5 mm
Break through time: > 30 min

in full contact:

Butyl rubber gloves.
Glove material : Butyl rubber
Layer thickness : 0,70 mm
Break through time: > 480 min

The protective gloves to be used must comply with the specifications of EC directive 89/686/EEC and the resultant standard EN374. This recommendation applies only to the product stated in this safety data sheet and supplied by us as well as to the purpose specified by us. When dissolving in or mixing with other substances and under conditions deviating from those stated in EN374 please contact the supplier of CE-approved gloves.

Eye/face protection : tightly fitting safety glasses

Body Protection : Protective clothing

Additional advice on system design : Use under strictly controlled conditions.

Hygiene measures : Do not eat, drink or smoke during work time.
Keep away from foodstuffs and beverages.
After worktime and during work intervals the affected skin areas must be thoroughly cleaned.

Laboratory

Respiratory protection : Handling in a fume cupboard.

Hand protection : In splash contact:
 Nitrile rubber gloves.

Eye/face protection : Safety glasses with side protection shield.

Body Protection : Dedicated working clothes.

Hygiene measures : Wash hands before breaks and at the end of workday.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties:

Form : Liquid

Boiling point : not determined

Flash point : not determined

Ignition temperature : not determined

Autoignition temperature : not determined

Thermal decomposition : not determined

Lower explosion limit : not determined

Upper explosion limit : not determined

Minimum ignition energy : not determined

Vapor pressure : not determined

Density : not determined

Solubility in water : not determined

pH value : not determined

Octanol/water partition coefficient : not determined

Viscosity (dynamic) : not determined

Viscosity (kinematic) : not determined

9.2. Other information:

SECTION 10: Stability and reactivity

10.3. Possibility of hazardous reactions : No hazardous reactions known.

10.6. Hazardous decomposition products : No data available

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute inhalation toxicity : No data available for mixture.

Acute dermal toxicity : No data available for mixture.

Acute oral toxicity : No data available for mixture.

Skin corrosion/irritation : No data available for mixture.

Serious eye damage/eye irritation : No data available for mixture.

Respiratory or skin sensitisation : No data available for mixture.

Specific target organ toxicity (STOT) - Single exposure : No data available for mixture.

Aspiration hazard : No data available for mixture.

Chronic/Long-term toxicity

Repeated Dose Toxicity : No data available for mixture.

Germ cell mutagenicity : No data available for mixture.

Carcinogenicity : No data available for mixture.

Reproductive toxicity : No data available for mixture.

Specific target organ toxicity (STOT) - repeated exposure : No data available for mixture.

Ingredients :

Name	CAS-No. (EC-No.)	Type and origin	Source
Benzyl alcohol	100-51-6 (202-859-9)	Acute oral toxicity: LD50 (Rat): 1.230 mg/kg	RTECS
Benzyl alcohol	100-51-6 (202-859-9)	Acute oral toxicity: LD50 (Rat): 3.100 mg/kg	Roth (WGK)
Benzyl alcohol	100-51-6 (202-859-9)	Acute inhalation toxicity: LC50 (Rat 8 h): 1000 ppm(V)	Roth (WGK)
Benzyl alcohol	100-51-6 (202-859-9)	Acute inhalation toxicity: LC50 (Rat): > 500 mg/m³	RTECS
Benzyl alcohol	100-51-6 (202-859-9)	Acute inhalation toxicity: LC50 (Rat 4 h): 4.178 mg/l	SDS of Supplier
Benzyl alcohol	100-51-6 (202-859-9)	Acute inhalation toxicity: LC50 (Rat 4 h): approx. 8,8 mg/l Cough	SDS of Supplier
Benzyl alcohol	100-51-6 (202-859-9)	Acute dermal toxicity: LD50 (rabbit): 2.000 mg/kg	RTECS
Benzyl alcohol	100-51-6 (202-859-9)	Germ cell mutagenicity: Not mutagenic in Ames Test	SDS of Supplier
Enoxaparine Sodium	679809-58-6 (696-630-4)	Acute oral toxicity: LD50 (Rat): 4.850 mg/kg	RTECS

Enoxaparine Sodium	679809-58-6 (696-630-4)	Acute oral toxicity: LD50 (Rat): > 5.000 mg/kg	Aventis Pharma France
Enoxaparine Sodium	679809-58-6 (696-630-4)	Acute inhalation toxicity: not determined	
Enoxaparine Sodium	679809-58-6 (696-630-4)	Acute dermal toxicity: not determined	
Enoxaparine Sodium	679809-58-6 (696-630-4)	Acute intravenous toxicity (IV) (LD50 Rats):350 mg/kg	RTECS
Enoxaparine Sodium	679809-58-6 (696-630-4)	Aspiration hazard: Not applicable	
Enoxaparine Sodium	679809-58-6 (696-630-4)	Repeated Dose Toxicity: This information is not available.	
Enoxaparine Sodium	679809-58-6 (696-630-4)	Germ cell mutagenicity: Not mutagenic in Ames Test In vivo chromosomal aberrations test negative. Mouse lymphoma assay (MLA) negative.	
Enoxaparine Sodium	679809-58-6 (696-630-4)	Carcinogenicity: not determined	
Enoxaparine Sodium	679809-58-6 (696-630-4)	Reproductive toxicity: No adverse effects on fertility in animal studies. No teratogenic, embryotoxic nor foetotoxic effects observed in animal studies.	

SECTION 12: Ecological information

12.1. Toxicity:

Acute Fish toxicity : No data available for mixture.

Acute invertebrates toxicity : No data available for mixture.

Bacteria toxicity : No data available for mixture.

12.2. Persistence and degradability:

Biological degradability : No data available for mixture.

12.3. Bioaccumulative potential:

Bioaccumulation : No data available for mixture.

12.4. Mobility in soil:

Behaviour in environmental compartments : No data available for mixture.

12.5. Results of PBT and vPvB assessment:

Results of PBT and vPvB assessment : This mixture contains no substance considered to be persistent, bioaccumulating and toxic (PBT).

12.6. Other adverse effects:

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Note : Do not allow to enter soil, waterways or waste water

Ingredients :

Name	CAS-No. (EC-No.)	Type and origin	Source
Benzyl alcohol	100-51-6 (202-859-9)	Biological degradability: 92 - 96 % Readily biodegradable. Testing period: 14 Days Method: OECD 301 C	SDS of Supplier
Benzyl alcohol	100-51-6 (202-859-9)	Fish (LC50): 646 mg/l Species: golden orfe Exposure duration: 48 h	Roth (WGK)
Benzyl alcohol	100-51-6 (202-859-9)	Fish (LC50): 460 mg/l Species: fish Exposure duration: 96 h	SDS of Supplier
Benzyl alcohol	100-51-6 (202-859-9)	Fish: Exposure duration: 3 h	
Benzyl alcohol	100-51-6 (202-859-9)	Daphnia (EC50): 400 mg/l Species: Daphnia magna Exposure duration: 24 h	SDS of Supplier
Benzyl alcohol	100-51-6 (202-859-9)	Daphnia (LC50): 360 mg/l Species: Daphnia (water flea) Exposure duration: 48 h	SDS of Supplier
Benzyl alcohol	100-51-6 (202-859-9)	Daphnia (EC50): 230 mg/l Species: Daphnia magna (Water flea) Exposure duration: 48 h Method: OECD 202	SDS of Supplier
Benzyl alcohol	100-51-6 (202-859-9)	Daphnia (EC50): 23 mg/l Exposure duration: 48 h	SDS of Supplier
Benzyl alcohol	100-51-6 (202-859-9)	Algae (EC50): 79 mg/l Species: Scenedesmus quadricauda Exposure duration: 3 h	Roth (WGK)
Benzyl alcohol	100-51-6 (202-859-9)	Algae (IC50): 700 mg/l Species: Pseudokirchneriella subcapitata Exposure duration: 72 h	SDS of Supplier
Benzyl alcohol	100-51-6 (202-859-9)	Algae (EC50): 700 mg/l Species: Pseudokirchneriella subcapitata Exposure duration: 72 h Method: OECD 201	SDS of Supplier
Benzyl alcohol	100-51-6 (202-859-9)	Algae : 35 mg/l Exposure duration: 3 h	SDS of Supplier
Benzyl alcohol	100-51-6 (202-859-9)	Bacteria toxicity (EC50): 390 mg/l Species: Bacteria Exposure duration: 24 h	SDS of Supplier
Benzyl alcohol	100-51-6 (202-859-9)	Behaviour in environmental compartments: On the basis of the partition coefficient n-octanol/water (log pow) no accumulation in organisms is expected	
Enoxaparine Sodium	679809-58-6 (696-630-4)	Biological degradability: 90 % Testing period: 28 d Method: OECD 301A / ISO 7827 The product is readily biodegradable according to OECD criteria.	Aventis Pharma France

Name	CAS-No. (EC-No.)	Type and origin	Source
Enoxaparine Sodium	679809-58-6 (696-630-4)	Fish: not determined	
Enoxaparine Sodium	679809-58-6 (696-630-4)	Daphnia (EC50): > 100 mg/l Species: Daphnia magna Exposure duration: 48 h Method: Tested according to Directive 92/69/EEC.	Sanofi-Aventis France
Enoxaparine Sodium	679809-58-6 (696-630-4)	Algae (EC50): > 100 mg/l Species: Desmodesmus subspicatus Exposure duration: 72 h Method: OECD 201	CIT
Enoxaparine Sodium	679809-58-6 (696-630-4)	Algae (NOEC): >= 100 mg/l Species: Scenedesmus subspicatus Exposure duration: 72 h Method: OECD 201	CIT
Enoxaparine Sodium	679809-58-6 (696-630-4)	Bacteria toxicity : not determined	
Enoxaparine Sodium	679809-58-6 (696-630-4)	Behaviour in environmental compartments: No known data.	

SECTION 13: Disposal considerations

13.1. Waste treatment methods:

- Product : In accordance with regulations for special waste, must be taken to an authorised special waste incineration plant.
Harmful emissions must be removed by flue gas scrubbing
- Uncleaned packaging : Packaging that cannot be cleaned should be disposed off as product waste

SECTION 14: Transport information

14.1. UN number

ADR

Not classified as dangerous in the meaning of transport regulations.

RID

Not classified as dangerous in the meaning of transport regulations.

IMDG

Not classified as dangerous in the meaning of transport regulations.

IATA

Not classified as dangerous in the meaning of transport regulations.

14.2. UN proper shipping name

ADR

Not classified as dangerous in the meaning of transport regulations.

RID

Not classified as dangerous in the meaning of transport regulations.

IMDG

Not classified as dangerous in the meaning of transport regulations.

IATA

Not classified as dangerous in the meaning of transport regulations.

14.3. Transport hazard class

ADR

Not classified as dangerous in the meaning of transport regulations.

RID

Not classified as dangerous in the meaning of transport regulations.

IMDG

Not classified as dangerous in the meaning of transport regulations.

IATA

Not classified as dangerous in the meaning of transport regulations.

14.4. Packing group

ADR

Not classified as dangerous in the meaning of transport regulations.

RID

Not classified as dangerous in the meaning of transport regulations.

IMDG

Not classified as dangerous in the meaning of transport regulations.

IATA

Not classified as dangerous in the meaning of transport regulations.

14.5. Environmental hazards

ADR

Not classified as dangerous in the meaning of transport regulations.

RID

Not classified as dangerous in the meaning of transport regulations.

IMDG

Not classified as dangerous in the meaning of transport regulations.

IATA

Not classified as dangerous in the meaning of transport regulations.

14.6. Special precautions for user

For personal protection see section 8.

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

No data available

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture:

15.2. Chemical safety assessment:

A Chemical Safety Assessment is not required for this substance.

SECTION 16: Other information

Full text of H-Statements referred to under sections 3:

H302	Harmful if swallowed.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.

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The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

Note: major information modified since the last version of the sheet is marked by a vertical line in front of the relevant change.

Definition of Sanofi-OEB:

OEB is the occupational exposure band with the following levels (solids - a similar but distinct scale is used for liquids, named OEB V):

Occupational Exposure Band	Occupational Exposure Level
OEB 1	> 1000 µg/m ³
OEB 2	100 - 1000 µg/m ³
OEB 3	10 – 100 µg/m ³
OEB 4	1 – 10 µg/m ³
OEB 5	< 1 µg/m ³

Additional notations may be applied as suffixes to the OEL/OEB and are used to communicate additional information that is not directly indicated by the OEL/OEB classifications. This information is necessary to perform an efficient risk assessment and determine the correct exposure controls. The meanings of the suffixes is explained in this way:

Notation/Suffixes	Danger
G1	Reprotoxic hazard for pregnant women. Exposure below the OEL is acceptable.
G2	Reprotoxic hazard for pregnant women. Exposure even below the OEL is not acceptable.
Sr	Respiratory sensitization hazard with serious potential consequences (anaphylactic reactions).
Sk	Specific dermal hazard (High dermal absorption / Danger of skin sensitization).
Cor	Corrosive compound - Important dermal and ocular hazard If corrosive compounds.