Safety data sheet

Levemir® Flexpen®, Levemir® 10 ml vial

1. Identification of the substance/preparation and of the company/undertaking

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2. Hazards identification

The product shall not be classified as hazardous according to (EC) No. 1272 / 2008, EU GHS/ CLP.

Additional information
No special risk if used in accordance with the instructions of the supplier.

3. Composition/information on ingredients

REACH registration number	CAS No./ Einecs no.	Substances	Classification/ CLP-classification	w/w%
-	169148-63-4	Aqueous solution for injection contains: Insulin Detemir	Not classified	-

Please see section 16 for the full text of R-phrases and H-phrases.

4. First aid measures

Inhalation
Remove to fresh air. If breathing is irregular, call a physician immediately.

Ingestion
When swallowed, seek medical attention and show the physician the package insert.
Not expected to be active orally (hypoglycemia). Seek medical attention if symptoms appear.

Skin
Wash with soap and water. Seek medical attention if irritation develops.

Eyes
Flush eyes with water for 15 minutes. If irritation develops, seek medical attention.

Other information
If in doubt, contact the doctor or emergency room. Always carry this manual or label.

5. Fire-fighting measures

The product is not readily flammable. Avoid breathing vapors and flue gases - seek fresh air.
Fire Fighting Extinguishing Media: In case of fire use foam, waterspray, dry chemical or CO2.

6. Accidental release measures

Use the same personal protective equipment as stated in section 8. Mop up spillage with a cloth. Dam spill and collect with sand or other absorbent material and place in suitable waste containers. For information on disposal please see item 13.

7. Handling and storage

Handling

See section 8 for information about precautions for use and personal protective equipment.

Storage

Keep refrigerated at 2-8 °C (36-46 °F). Do not freeze. Keep the cartridge in the outer carton in order to protect from light and heat. After first opening or carried as a spare: Do not refrigerate. Store below 30°C. Store according to product instruction to prevent degradation.

8. Exposure controls/ personal protection

Precautions for use

Work under effective process ventilation (e.g. local exhaust ventilation).

There must be access to running water and eye wash.

Respiratory protection

Not normally required.

Gloves and protective clothing

PVC gloves, nitril rubber or similar of greater protection are recommended for waste clean-up and manufacturing and packaging operations.

Eye protection

Clean-up, manufacturing and packaging operations may require safety glasses or goggles if there is a risk of splashing.

Occupational exposure limits

Contains no substances subject to reporting requirements.

9. Physical and chemical properties

Appearance: Clear, colourless, neutral solution

10. Stability and reactivity

No known incompatibilities. No known hazardous decomposition products.

11. Toxicological information

Acute

Inhalation
Not investigated. Inhalation of sprit mist containing protein may cause sensitization.

Ingestion
Not expected to be active orally. Absorption is not expected. Ingestion may cause discomfort.

Skin contact
May cause irritation by the active substance or any of the excipients.

Eye contact
May cause irritation. Avoid contact with the eyes.

Risk of sensitization
Hypersensitivity to the active substance or to any of the excipients.

Long-term effects
Repeated dose studies in animals did not identify any target organ toxicity.

May cause damage to the reproductive system
Levemir® indicate no adverse effects of insulin detemir on pregnancy and no malformative or feto/neonatal toxicity of insulin detemir.

May cause genetic damage
Proteins are not expected to have any genotoxic potential. None of the excipients in Levemir® posses any genotoxic potential.

12. Ecological information

Do not discharge large quantities of concentrated spills and residue into drains.

13. Disposal considerations

The product is not hazardous waste .
It is recommended that large quantities of waste and waste disposed of through the local receiving station with the following specifications.
Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

14. Transport information

The product is not covered by the rules for the transport of dangerous goods by road and sea according to ADR and IMDG.

15. Regulatory information

Hazard designation: It has been assessed that the product shall not be classified according to (EC) No. 1272 / 2008, EU GHS/ CLP.

Contains
Insulin Detemir

Supplemental information
None.

Chemical safety assessment
Chemical safety assessment has not been performed.

16. Other information

Restrictions on use
None.

Training requirement
No special training is necessary but a thorough knowledge of this safety data sheet is assumed.

Sources used

Other information
The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions.

Full text of the R-phrases that are stated in section 3.
No R-phrases.

Full text of the H-phrases that are stated in section 3.
No H-phrases.