

Novo Nordisk A/S	DIRECTIONS FOR USE / MATERIAL SAFETY DATA SHEET according to 91/155/EEC
	LEVEMIR®10 ml, LEVEMIR FLEXPEN

Trade name	Insulin Detemir	CAS-no.	169148-63-4
Chemical name	Lys ^{B29} (N ^ε -tetra-decanoyl) des(B30) human insulin (contains 0,30 % (w/v) phenol)	EC-no.	-
Novo Nordisk item no.	368712, 643910, 5967800		
Company	Novo Nordisk Inc. 100 College Road West, Princeton, New Jersey 08540 USA,		
Emergency telephone no.	Tel.: +1 609 987 5800		

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Hazardous ingredients	Concentration	Classification
108-95-2 Phenol	0,30 % (w/v)	T; R23/24/25-C;R34-48/20/21/22-68

HAZARDS IDENTIFICATIONS	3
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Potential Health Effects	Inhalation of aerosols of Insulin Detemir may result in a mild temporary decrease of the blood sugar level (hypoglycaemia). Exposure to Insulin Detemir is not known to cause adverse health effects.
Inflammatory Properties	Insulin Detemir is not combustible.

FIRST AID MEASURES	4
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After swallowing	Rinse out mouth thoroughly with water and give plenty of water to drink. Do NOT provoke vomiting. Seek immediately medical advice.
Skin contact	Remove contaminated clothes and wash contaminated skin thoroughly with plenty of water for at least 15 minutes. Seek immediately medical advice.
Eyes	Rinse the eye immediately with plenty of water for at least 15 minutes with the eyelid held wide open. Seek immediately medical advice.
Inhalation	Go outside to breathe fresh air.

PRECAUTIONS IN CASE OF FIRE	5
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No special precaution.	Continued
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ACCIDENTAL RELEASE MEASURES	6
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Use personal protection means when removing the spillage. (See item 8). Clean up affected area.

HANDLING AND STORAGE	7
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Insulin Detemir must be kept in refrigerator at 2 - 8°C (36 – 46 °F) in tightly closed original packing.

EXPOSURE CONTROL / PERSONAL PROTECTION MEANS	8
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Limit value		Smell limit	-
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Avoid inhalation of aerosols. If necessary, use breathing protection (P2-particle-filter, authorized for aerosols). Use protection gloves (e.g. Nitrilrubber (Solvex)). There must be easy access to plentiful water supply, emergency- or hand shower/eye rinsing bottle.

PHYSICAL AND CHEMICAL CHARACTERISTICS	9
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Appearance	Levemir FlexPen prefilled with 3 mL (300 units) of Levemir	Water-solubility	Slightly soluble
Chemical formula	C ₂₆₇ H ₄₀₂ N ₆₄ O ₇₆ S ₆	Molecular weight	5916,9 Dalton
Density	No information	Freezing point	No information
Boiling point	No information	Flash point	No information

STABILITY AND REACTIVE POWER	10
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Insulin Detemir is stable under normal circumstances.

TOXICOLOGICAL DATA	11
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LD₅₀-value, oral (rat)		LD₅₀-value, dermal (rat)	-
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Effects on long-term:	No	Under suspicion	Yes	Contradictory information	None
Carcinogenic	X				
Allergy (contact allergy)	X				
Allergy (inhalation allergy)	X				
Teratogenic	X				
Nerve damaging	X				

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Insulin Detemir does no harm to the environment.

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This material and its container must be disposed of as hazardous waste. Spillage and waste are to be collected in proper receptacles and disposed at an approved site according to existence of local regulations regarding disposal.

INFORMATION ON TRANSPORT	14
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UN.no	-	Shipping name	-
ADR	Not dangerous goods	IMDG	Not dangerous goods
RID	Not dangerous goods	IATA	Not dangerous goods.

REGULATORY INFORMATION	15
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Class of risks	Not classified	Symbol:			
R-phrases:	No R-phrases				
S-phrases:	No S-phrases				

No special regulations.

OTHER INFORMATION	16
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No demand for special education, but persons handling Insulin Detemir must be familiar with the instructions mentioned in these Material Safety Data.