

Novo Nordisk A/S	DIRECTIONS FOR USE / MATERIAL SAFETY DATA SHEET according to 91/155/EEC		
	Levemir[®] (insulin detemir [rDNA origin] injection)		

Trade name	Levemir [®]	CAS-no.	169148-63-4
Chemical name	Lys ^{B29} (N ^ε -tetra-decanoyl) des(B30) human insulin	EC-no.	
Novo Nordisk item no.			
Company	Novo Nordisk Inc. 100 College Road West, Princeton, New Jersey 08540 USA,		
Emergency telephone no.	Tel.: +1 609 987 5800		
COMPOSITION / INFORMATION ON CONTENTS			2
Hazardous ingredients	Concentration	Classification	
None			
HAZARDS IDENTIFICATIONS			3
Potential Health Effects	Inhalation of dust/aerosols of Levemir [®] may result in a mild temporary decrease of the blood sugar level (hypoglycaemia). Exposure to Levemir [®] is not known to cause adverse health effects.		
Inflammatory Properties	Levemir [®] is flammable.		
FIRST AID MEASURES			4
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
ACCIDENTAL RELEASE MEASURES				6
Use personal protection means when removing the spillage. (See item 8) . Clean up affected area.				
HANDLING AND STORAGE				7
Levemir® must be kept in refrigerator at 2 - 8°C (36 – 46 °F) in tightly closed original packing.				
EXPOSURE CONTROL / PERSONAL PROTECTION MEANS				8
Limit value		Smell limit	-	
Avoid inhalation of dust/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
Appearance	White crystalline powder	Water-solubility	25 mg/ml	
Chemical formula	C ₂₆₇ H ₄₀₂ N ₆₄ O ₇₆ S ₆	Molecular weight	5916,9 Dalton	
Density	(at 25°C)	Freezing point	No information	
Boiling point	No information	Flash point	No information	
Log P octanol/water	No information	Vapour pressure	No information	
pH	7,7 (at 20° C)			
STABILITY AND REACTIVE POWER				10
Levemir® is stable under normal circumstances.				

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LD ₅₀ -value, oral (rat)		LD ₅₀ -value, dermal (rat)	-		
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

ENVIRONMENT INFORMATION	12
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Levemir® does no harm to the environment.

DISPOSAL CONSIDERATIONS	13
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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				

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No special regulations.	
OTHER INFORMATION	16
No demand for special education, but persons handling Levemir [®] must be familiar with the instructions mentioned in these Material Safety Data.	