

Novo Nordisk A/S	DIRECTIONS FOR USE / MATERIAL SAFETY DATA SHEET according to 91/155/EEC			
		Norditropin SimpleXx[®] 5 mg/1.5 ml Norditropin SimpleXx[®] 10 mg/1.5 ml Norditropin SimpleXx[®] 15 mg/1.5 ml		
Trade name	Norditropin SimpleXx [®] Norditropin NordiFlex [®]	CAS-NO.		
Chemical name	Aqueous solution for injection containing Somatropin (further more contains 0,30 % (w/v) phenol))	EU-NO.	-	
Synonyms	-	INDEX-NO.	-	
Novo Nordisk item no.	5 mg/1.5 ml: 5-2070-02; 10 mg / 1.5 ml: 5-2071-00; 15 mg / 1.5 ml: 5-2072-02 30 mg / 3 ml (Norditropin NordiFlex [®]): 5-2083-00			
COMPOSITION / INFORMATION ON CONTENTS				2
Class of risks	Not classified (in accordance to EC Directive 91/155/EØF)	Hazard symbols		
Risk-phrases	No R-phrases			
Safety-phrases	No S-phrases			
HAZARDS IDENTIFICATIONS				3
HAZARDOUS PROPERTIES Acute effects	Somatropin is a natural human hormon, produced in the hypophysis throughout the life. Norditropin SimpleXx [®] is not expected to cause any acute hazards when the product is handled according to good manufacturing practice.			
Chronicle effects	Norditropin SimpleXx [®] is not expected to cause any chronicle hazards when the product is handled according to good manufacturing practice.			
FLAMMABLE PROPERTIES	Norditropin SimpleXx [®] (aqueous solution) is not combustible.			
FIRST AID MEASURES				4
Consumption	Rinse out mouth thoroughly with water and give plenty of water. Norditropin SimpleXx [®] will decompose in the gastro-intestinal tract and will not be absorbed into the blood-stream.			
Inhalation	Go out into fresh air. Seek medical advice if respiratory symptoms occurs.			
Eye contact	Rinse out with water for at least 15 minutes. If necessary, seek medical attention.			
Skin contact	Remove contaminated clothes immediately and rinse contaminated skin for at least 15 minutes with water and soap. In further problems, seek medical attention.			

Continued

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PRECAUTIONS IN CASE OF FIRE			5
No special precautions.			
ACCIDENTIAL RELEASE MEASURES			6
Absorb liquid spill into an absorbent e.g.: sand/vermiculite. Clean contaminated surfaces with excess of water. Use personal protection during the clean-up.			
HANDLING AND STORAGE			7
Norditropin SimpleXx [®] must be kept at 2 – 8 °C in tightly closed original packing.			
EXPOSURE CONTROLS / PERSONAL PROTECTION			8
Limit value	none	Smell limit value	-
Avoid inhalation of aerosols. If necessary, use breathing protection (P2-particle filter, authorized for aerosols). Avoid contact with the skin. Wear gloves (e.g. PVC-disposable gloves). There must be easy access to running water, emergency water spray / eye-wash bottle on the spot.			
PHYSICAL AND CHEMICAL PROPERTIES			9
Chemical formula	C ₉₉₀ H ₁₅₂₈ N ₂₆₂ O ₃₀₀ S ₇	Water-solubility	-
Appearance	Colourless liquid with a smell of phenol	Molecular weight	22125 Da
Density	1, 01 g/ml ved 25° C	Melting point	Not applicable
Boiling point	100°C	Flash point	Not applicable
Viscosity	-	Vapour pressure	Not applicable
Explosion limits	Not applicable	Auto-ignition point	Not applicable
pH value	Neutral	Octanol/water coefficient	Not applicable
STABILITY AND REACTIVITY			10
Norditropin SimpleXx [®] is stable under normal circumstances.			

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TOXICOLOGICAL DATA					11
LD ₅₀ -value, oral (rat)	-		LD ₅₀ -value, dermatological (rat)	-	
Long-term adverse effects:	No	Under suspicion	Yes	Contradictory information	No information
Carcinogenic	X				
Allergy (contact allergy)	X				
Allergy (inhalation allergy)	X				
Teratogenic	x				
Nerve-damaging					X
ENVIRONMENT INFORMATION					12
Norditropin SimpleXx [®] does no harm to the environment.					
WASTE DISPOSAL CONSIDERATIONS					13
Spillage and waste are to be collected in proper receptables. Dispose at an approved site according local regulations regarding disposal.					
Chemical waste group	Z		Chemical waste card	-	
TRANSPORT INFORMATION					14
ADR	Not dangerous goods		IMDG	Not dangerous goods	
RID	Not dangerous goods		IATA	Not dangerous goods	
UN - no.	-		Safety card no.	-	
REGULATORY INFORMATION					15
No special regulations.					
OTHER INFORMATION					16
There are no special demands for education, but persons handling Norditropin SimpleXx [®] should be familiar with the instructions mentioned in these directions for use.					