

Safety Data Sheet

NutropinAQ(R) Pen Cartridge and NuSpin (20 mg/2 ml)

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

1.1. Product identifier

Product name NutropinAQ(R) Pen Cartridge and NuSpin (20 mg/2 ml)
Product code SAP-10130607
Synonyms - NUTROPIN AQ 20mg

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

Use - solution for subcutaneous injection

1.3. Details of the supplier of the safety data sheet

Company information	Enquiries: Genentech, Inc. 1 DNA Way South San Francisco USA-CA 94080 United States of America	Local representation:
	Phone 001-(650) 225-1000 E-Mail info.sds@roche.com US Chemtrec phone: (800)-424-9300	

1.4. Emergency telephone number

Emergency telephone number US Chemtrec phone: (800)-424-9300

SECTION 2: Hazards identification

Classification of the substance or mixture / Label elements

GHS Classification no classification and labelling according to GHS

Other hazards

Note - no information available

SECTION 3: Composition/information on ingredients

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Ingredients	Concentration	GHS-Classification (pure ingredient)
Somatropin 12629-01-5	1 %	
SECTION 4: First aid measures		
4.1. Description of first aid measures		
Eye contact	- rinse immediately with tap water for 10 minutes - open eyelids forcibly	
Skin contact	- remove immediately contaminated clothes, wash affected skin with water and soap - do not use any solvents	
Inhalation	- remove the casualty to fresh air and keep him/her calm - in the event of symptoms get medical treatment	
4.2. Most important symptoms and effects, both acute and delayed		
Note	- no information available	
4.3. Indication of any immediate medical attention and special treatment needed		
Note to physician	- treat symptomatically	
SECTION 5: Firefighting measures		
5.1. Extinguishing media		
Suitable extinguishing media	- adapt extinguishing media to surrounding fire conditions	
Flash point (liquid)	not applicable	
5.2. Special hazards arising from the substance or mixture		
Specific hazards	- no particular hazards known	
5.3. Advice for firefighters		
Protection of fire-fighters	- precipitate gases/vapours/mists with water spray	
SECTION 6: Accidental release measures		
6.1. Personal precautions, protective equipment and emergency procedures		
Personal precautions	- no special precautions required	

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6.2. Environmental precautions

Environmental protection - no special environmental precautions required

6.3. Methods and material for containment and cleaning up

Methods for cleaning up - collect liquids by means of sand, earth or another suitable material

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Suitable materials - glass

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions - 2 - 8 °C
- protected from light
- do not shake solution
- do not freeze

Validity - 28 d, 2 to 8 °C, for opened kits
- see expiry date on the label

Packaging materials - cartridges

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Threshold value (Roche) air - IOEL (Internal Occupational Exposure Limit): 0.02 mg/m³ *1

8.2. Exposure controls

Respiratory protection - Respiratory protection is recommended as a precaution to minimize exposure. Effective engineering controls are considered to be the primary means to control worker exposure. Respiratory protection should not substitute for feasible engineering controls.
- in case of open handling or accidental release:
particle mask or respirator with independent air supply

Hand protection - protective gloves (eg made of neoprene, nitrile or butyl rubber)

Eye protection - safety glasses

*1 referring to: Somatotropin

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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Color	colorless
Form	clear solution sterile liquid

9.2. Other information

Note - no information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Note - no information available

10.2. Chemical stability

Note - no information available

10.3. Possibility of hazardous reactions

Note - no information available

10.4. Conditions to avoid

Conditions to avoid - light

10.5. Incompatible materials

Note - no information available

10.6. Hazardous decomposition products

Note - no information available

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity - LD₅₀ 38'900 mg/kg (oral, rat) *2

Mutagenicity - may induce chromosomal aberrations in vitro (in vitro test system) *1

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- Potential Health Effects
- Exposure: Inhalation, Ingestion, Skin contact, Eye contact
 - Target Organs: Central nervous system, Immune System, Skeletal system
 - Acute Effects: May cause musculoskeletal effects., Signs and symptoms may include muscle weakness or pain and skeletal abnormalities., This material is not likely to be significantly absorbed via occupational routes of entry due to its chemical structure and large molecular weight.
 - Chronic Effects: May cause allergic reactions., May cause brain tumors.
 - Carcinogenicity: not listed by NTP, IARC or OSHA

*1 referring to: Somatropin
*2 referring to: Polysorbate 20

SECTION 12: Ecological information

12.1. Toxicity

- Ecotoxicity
- barely toxic for planktonic crustaceans (Ceriodaphnia dubia)
EC₅₀ (48 h) 735.54 mg/l *3

12.2. Persistence and degradability

- Ready biodegradability
- readily biodegradable
97.2 %, 5 d *2

12.3. Bioaccumulative potential

- Note
- no information available

12.4. Mobility in soil

- Note
- no information available

12.5. Results of PBT and vPvB assessment

- Note
- no information available

12.6. Other adverse effects

- Note
- no information available

*2 referring to: Polysorbate 20
*3 referring to: Sodium citrate

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SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues - observe local/national regulations regarding waste disposal

SECTION 14: Transport information

Note - not classified by transport regulations, proper shipping name non-regulated

SECTION 15: Regulatory information

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

TSCA Status - FDA Exemption - not on inventory

Reporting Requirements - The United States Environmental Protection Agency (USEPA) has not established a Reportable Quantity (RQ) for releases of this material.
- In New Jersey, report all releases which are likely to endanger the public health, harm the environment or cause a complaint to the NJDEPE Hotline (1-609-292-5560) and to local officials.
- State and local regulations vary and may impose additional reporting requirements.

SECTION 16: Other information

Edition documentation - changes from previous version in sections 3, 16

The information in this safety data sheet is based on current scientific knowledge. It should not be taken as expressing or implying any warranty concerning product characteristics.