



Material Safety Data Sheet

# NutropinAQ(R) Pen Cartridge and NuSpin (10 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 (10 mg/2 ml)  
Product code SAP-10130606  
Synonyms - NUTROPIN AQ 10mg

### 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: Local representation:  
Hoffmann-La Roche Inc.  
340 Kingsland Street  
USA-Nutley, N.J. 07110-1199  
United States of America  
  
Phone 001-973/235 50 00  
E-Mail info.sds@roche.com  
  
US Emergency phone: (800)-827-6243  
US Chemtrec phone: (800)-424-9300

### 1.4. Emergency telephone number

Emergency telephone number US emergency phone: (800)-827-6243

## SECTION 2: Hazards identification

### Emergency Overview

Form clear solution  
sterile liquid  
Color colorless  
Hazard Overview - May cause allergic reactions.

# NutropinAQ(R) Pen Cartridge and NuSpin (10 mg/2 ml)

- 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

## 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

Ingredients	Concentration
Somatropin CAS: 12629-01-5	0.5 %

## 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

# NutropinAQ(R) Pen Cartridge and NuSpin (10 mg/2 ml)

## 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

### 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

# NutropinAQ(R) Pen Cartridge and NuSpin (10 mg/2 ml)

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

Note - no information available

### 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

## 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

# NutropinAQ(R) Pen Cartridge and NuSpin (10 mg/2 ml)

## 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 - LD<sub>50</sub> 38'900 mg/kg (oral, rat) \*1

Mutagenicity - may induce chromosomal aberrations in vitro (in vitro test system) \*2

\*1 referring to: Polysorbate 20

\*2 referring to: Somatropin

## SECTION 12: Ecological information

### 12.1. Toxicity

Ecotoxicity - barely toxic for planktonic crustaceans (Ceriodaphnia dubia)  
EC<sub>50</sub> (48 h) 735.54 mg/l \*3

### 12.2. Persistence and degradability

Ready biodegradability - readily biodegradable  
97.2 %, 5 d \*1

### 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

# NutropinAQ(R) Pen Cartridge and NuSpin (10 mg/2 ml)

## 12.6. Other adverse effects

Note - no information available

\*1 referring to: Polysorbate 20

\*3 referring to: Sodium citrate

## 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 - first edition

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.



Material 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: Local representation:  
Hoffmann-La Roche Inc.  
340 Kingsland Street  
USA-Nutley, N.J. 07110-1199  
United States of America  
  
Phone 001-973/235 50 00  
E-Mail info.sds@roche.com  
  
US Emergency phone: (800)-827-6243  
US Chemtrec phone: (800)-424-9300

### 1.4. Emergency telephone number

Emergency telephone number US emergency phone: (800)-827-6243

## SECTION 2: Hazards identification

### Emergency Overview

Form clear solution  
sterile liquid  
Color colorless  
Hazard Overview - May cause allergic reactions.

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

- 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

## 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

Ingredients	Concentration
Somatropin CAS: 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

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

## 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

### 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

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

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

Note - no information available

### 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

## 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

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

### 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 - LD<sub>50</sub> 38'900 mg/kg (oral, rat) \*1  
Mutagenicity - may induce chromosomal aberrations in vitro (in vitro test system) \*2

\*1 referring to: Polysorbate 20

\*2 referring to: Somatropin

## SECTION 12: Ecological information

### 12.1. Toxicity

Ecotoxicity - barely toxic for planktonic crustaceans (Ceriodaphnia dubia)  
EC<sub>50</sub> (48 h) 735.54 mg/l \*3

### 12.2. Persistence and degradability

Ready biodegradability - readily biodegradable  
97.2 %, 5 d \*1

### 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

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

## 12.6. Other adverse effects

Note - no information available

\*1 referring to: Polysorbate 20

\*3 referring to: Sodium citrate

## 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 - first edition

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**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1. Product identifier**

Product name NutropinAQ(R) NuSpin (5 mg/2 ml)  
Product code SAP-10130604

**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: Local representation:  
Hoffmann-La Roche Inc.  
340 Kingsland Street  
USA-Nutley, N.J. 07110-1199  
United States of America  
  
Phone 001-973/235 50 00  
E-Mail info.sds@roche.com  
  
US Emergency phone: (800)-827-6243  
US Chemtrec phone: (800)-424-9300

**1.4. Emergency telephone number**

Emergency telephone number US emergency phone: (800)-827-6243

**SECTION 2: Hazards identification****Emergency Overview**

Form clear solution  
sterile liquid  
  
Color colorless  
  
Hazard Overview - May cause allergic reactions.

## NutropinAQ(R) NuSpin (5 mg/2 ml)

- 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

### 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

Ingredients	Concentration
Somatropin CAS: 12629-01-5	0.25 %

## 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

## NutropinAQ(R) NuSpin (5 mg/2 ml)

### 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

#### 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

## NutropinAQ(R) NuSpin (5 mg/2 ml)

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

Note - no information available

#### 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

### 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

## NutropinAQ(R) NuSpin (5 mg/2 ml)

### 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 - LD<sub>50</sub> 38'900 mg/kg (oral, rat) \*1  
Mutagenicity - may induce chromosomal aberrations in vitro (in vitro test system) \*2

\*1 referring to: Polysorbate 20

\*2 referring to: Somatropin

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### 12.1. Toxicity

Ecotoxicity - barely toxic for planktonic crustaceans (Ceriodaphnia dubia)  
EC<sub>50</sub> (48 h) 735.54 mg/l \*3

### 12.2. Persistence and degradability

Ready biodegradability - readily biodegradable  
97.2 %, 5 d \*1

### 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

## NutropinAQ(R) NuSpin (5 mg/2 ml)

### 12.6. Other adverse effects

Note - no information available

\*1 referring to: Polysorbate 20

\*3 referring to: Sodium citrate

## 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

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