<table>
<thead>
<tr>
<th><strong>1.1. Product identifier</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product name</strong></td>
</tr>
<tr>
<td><strong>Product code</strong></td>
</tr>
<tr>
<td><strong>Synonyms</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>1.2. Relevant identified uses of the substance or mixture and uses advised against</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Use</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>1.3. Details of the supplier of the safety data sheet</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Company information</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>1.4. Emergency telephone number</strong></td>
</tr>
<tr>
<td>----------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Emergency telephone number</strong></td>
</tr>
</tbody>
</table>

**SECTION 2: Hazards identification**

<table>
<thead>
<tr>
<th><strong>Classification of the substance or mixture / Label elements</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>GHS Classification</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Other hazards</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Note</strong></td>
</tr>
</tbody>
</table>

**SECTION 3: Composition/information on ingredients**
## NutropinAQ(R) Pen Cartridge and NuSpin (20 mg/2 ml)

### Ingredients

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Concentration</th>
<th>GHS-Classification (pure ingredient)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Somatropin</td>
<td>1 %</td>
<td></td>
</tr>
<tr>
<td>12629-01-5</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 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
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: Somatropin
### SECTION 9: Physical and chemical properties

**9.1. Information on basic physical and chemical properties**

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Color</td>
<td>colorless</td>
</tr>
<tr>
<td>Form</td>
<td>clear solution</td>
</tr>
<tr>
<td></td>
<td>sterile liquid</td>
</tr>
</tbody>
</table>

**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**: \( \text{LD}_{50} \) 38'900 mg/kg (oral, rat) \(^2\)

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

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

### SECTION 12: Ecological information

#### 12.1. Toxicity

**Ecotoxicity**
- barely toxic for planktonic crustaceans (Ceriodaphnia dubia)  
  \[ EC_{50} (48 \text{ h}) = 735.54 \text{ mg/l} \]  

*3

#### 12.2. Persistence and degradability

**Ready biodegradability**
- readily biodegradable  
  \[ 97.2 \% \text{, } 5 \text{ d} \]  

*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
# 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.

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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.