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

## 1.1. Product identifier

<table>
<thead>
<tr>
<th>Product name</th>
<th>NutropinAQ(R) NuSpin (5 mg/2 ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product code</td>
<td>SAP-10130604</td>
</tr>
</tbody>
</table>

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

- solution for subcutaneous injection

## 1.3. Details of the supplier of the safety data sheet

<table>
<thead>
<tr>
<th>Company information</th>
<th>Enquiries: Genentech, Inc. 1 DNA Way South San Francisco USA-CA 94080 United States of America</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>E-Mail <a href="mailto:info.sds@roche.com">info.sds@roche.com</a></td>
</tr>
<tr>
<td></td>
<td>Phone 001-(650) 225-1000</td>
</tr>
<tr>
<td></td>
<td>US Chemtrec phone: (800)-424-9300</td>
</tr>
</tbody>
</table>

## 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**

- no information available

# SECTION 3: Composition/information on ingredients
**Ingredients**

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Concentration</th>
<th>GHS-Classification (pure ingredient)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Somatropin</td>
<td>0.25 %</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
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: 
  - LD$_{50}$: 38'900 mg/kg (oral, rat) $^2$
Mutagenicity: may induce chromosomal aberrations in vitro (in vitro test system) $^1$
**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

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**SECTION 12: Ecological information**

12.1. Toxicity

**Ecotoxicity**

- barely toxic for planktonic crustaceans (Ceriodaphnia dubia) 
  $EC_{50}$ (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.