Material safety data sheet

Sodium hyaluronate gel
(470kDa – 4200kDa)

Date 2013-03-11
(Previous 2012-04-23)

Product Specifications

1. Product identification

Product name
Sodium Hyaluronate Gel

Product use fields
Active ingredient for cosmetics, drugs or medical devices.

Expected uses
Hydration, Viscoelasticity

Manufacturer
RegenLab SA, En Budron B2, 1052 Le Mont, Switzerland

Phone
0041.21.864.01.10

Emergency phone
0041.44.251.51.51 (Tox Zentrum)

2. Hazards identification

Classification of the substance
Not classified as dangerous. No critical hazards to man and the environment.

Main hazards
None

Specific hazards
None

3. Composition / information on ingredients

Usual chemical name
Sodium Hyaluronate Gel

Hazardous ingredients
This product does not contain any hazardous ingredients.

Risk earnings relating to the substance
Without object

<table>
<thead>
<tr>
<th>Components</th>
<th>Classification</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Hyaluronate</td>
<td>Polysaccharides</td>
<td>Sodium Hyaluronate (Monograph N° 1472, European Pharmacopoeia)</td>
</tr>
<tr>
<td>CAS N° 9067-32-7 (9004-61-9 Hyaluronic acid)</td>
<td>No health or environmental hazard, no exposure limits</td>
<td>2% (w/v)</td>
</tr>
<tr>
<td>EC N° 618-620-0 (232-678-0 Hyaluronic acid)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sodium chloride</td>
<td></td>
<td>137 mM</td>
</tr>
<tr>
<td>CAS N° 7647-14-5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EC N° 231-598-3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dipotassium hydrogenorthophosphate</td>
<td></td>
<td>7.6 mM (± 0.43mM)</td>
</tr>
<tr>
<td>CAS N° 7758-11-4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EC N° 231-834-5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Potassium dihydrogenorthophosphate</td>
<td></td>
<td>2.38 mM (± 0.55mM)</td>
</tr>
<tr>
<td>CAS N° 7778-77-0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EC N° 231-913-4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Potassium chloride</td>
<td></td>
<td>2.7 mM</td>
</tr>
<tr>
<td>CAS N° 7447-40-7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EC N° 231-211-8</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

FOR CHEMICAL EMERGENCY
Spill, Leak, Exposure or Incident
Call INFOTRAC • 24-Hour Number:
1-800-535-5053 or +1-352-323-3500 (outside USA)
4. First aid measures

General advice
Consult a physician. Show this safety data sheet to the doctor in attendance.

Inhalation
If breathing, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

Skin contact
After contact with skin, wash with water and soap.

Eye contact
In case of contact with eyes, check for contact lenses and remove if present. Rinse immediately with plenty of water.

Ingestion
Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

5. Fire fighting measures

Not a fire or explosion hazard. The product itself does not burn. May be combustible at high temperature.

Suitable extinguishing media
Water, carbon dioxide

Unsuitable extinguishing media
No data

Specific hazards during fire fighting
Combustion products include COx, Oxides of phosphorus, Hydrogen chloride gas, Potassium oxides, Sodium oxides

Special protective equipment for fire-fighters
Wear self contained breathing apparatus for firefighting if necessary. Gas mask (CO)

6. Accidental release measures

Personal precautions
Use personal protective equipment (wear chemical safety goggles, appropriate protective gloves and clothing). Avoid dust formation and dust breathing. Avoid breathing vapors, mist or gas. Ensure adequate ventilation.

Environmental safety measures
None. No ecological problem.

Methods for cleaning up
In case of leak or overflow, dilute with water.

7. Handling and storage

Handling
Regarding the human health: no special precautions required. Avoid formation of aerosols.

Special cautions & Handling advices
Use with sterile gloves to prevent any microbiological contamination of the product. Hermetically seal the packaging after sampling.

Storage
Store in an airtight container, protected from light and humidity. Store in its original packaging tightly closed in a cool place.

Primary packaging material
Cosmetic or medical quality: low density polyethylene bag
8. Exposure controls / Personal protection

<table>
<thead>
<tr>
<th>Exposure limits values</th>
<th>No exposure limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure controls</td>
<td>Hygiene measures: Good industrial practices (do not drink, eat, or smoke while working). Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower. Use adequate ventilation (barrier to microbial contamination of the product).</td>
</tr>
<tr>
<td>Respiratory protection</td>
<td>Respiratory protection is not required. Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN 143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).</td>
</tr>
<tr>
<td>Eyes/face protection</td>
<td>Safety glasses with side-shields conforming to EN166. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).</td>
</tr>
<tr>
<td>Skin protection</td>
<td>Handle with gloves. Gloves must be inspected prior to use. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.</td>
</tr>
</tbody>
</table>

9. Physical and chemical characteristics

<table>
<thead>
<tr>
<th>Appearance</th>
<th>translucent gel</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor</td>
<td>Odorless</td>
</tr>
<tr>
<td>pH</td>
<td>7.2 - 7.6 at 25 °C</td>
</tr>
<tr>
<td>Boiling point</td>
<td>100°C</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not available</td>
</tr>
<tr>
<td>Explosives properties</td>
<td>None</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative density</td>
<td>Gel # 1 (water = 1)</td>
</tr>
<tr>
<td>Solubility</td>
<td>Soluble in water, insoluble in most organic solvents or fat</td>
</tr>
<tr>
<td>Partition coefficient (n-octanol/water)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Viscosity</td>
<td>5000-15000 mPa.s.</td>
</tr>
<tr>
<td>Vapor density</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

Other information:
- Self inflammability temperature and explosion hazards: Non flammable and non explosive product
- Decomposition temperature: Over 300°C

10. Stability and reactivity
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(Previous 2012-04-23)

The product is stable
Reactivity
Chemical stability
Possibility of hazardous reactions
Conditions to avoid
Materials to avoid
Hazardous decomposition products

No data available
No data available
No data available
High temperature, ionizing radiation, sun light (degradation of the product)
Strong acids. Oxidizing agents (degradation of the product)

11. Toxicological information

Toxicity
Acute oral toxicity
Tolerance tests (Cosmetic grade)
Cytotoxicity (Pharmaceutical grade)
Skin sensitization (Pharmaceutical grade)
Acute ocular irritation (Pharmaceutical grade)
Abnormal toxicity (Pharmaceutical grade)
Carcinogenicity (IARC)

NOT TOXIC SUBSTANCE
LD50 (oral, rat): more than 400 mg/kg (Bibliography).
Primary Cutaneous Irritation Index: not irritant. Ocular irritation Index: not irritant.
Not cytotoxic
No dermal reaction
No ocular irritation
No evidence of significant toxicity or mortality after injection
No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

12. Ecological information

BIODEGRADABLE, NO ECOLOGICAL PROBLEM.
Ecotoxicity
Mobility
Persistence and degradability
Bioaccumulative potential
Others adverse effects

No negative harmful effects
Not applicable
Fully biodegradable
Not applicable
None

13. Disposal consideration

No special appropriate methods of handling and disposal are needed.
Small amount may be washed down the drain with excess of water.

14. Transport information

Not classified as "Hazardous for transport". No special requirements.
15. Regulatory information

Not classified as “Hazardous substance” according to the EU and US regulations.
According to REACH regulation, the substance is classified as “naturally occurring polymer”.

16. Other information

| Product use fields | Active ingredient for cosmetics, drugs or medical devices |