SECTION 1: IDENTIFICATION

1.1. Product Identifier
Product Form: Mixture
Product Name: Adequan® I.A.
Product Code: Single-Dose: 995-70; Multi-Dose: 959-01

1.2. Intended Use of the Product
Use of the substance/mixture: For the intra-articular treatment of non-infectious degenerative and/or traumatic joint dysfunction and associated lameness of the carpal joint in horses.

1.3. Name, Address, and Telephone of the Responsible Party
Company
Luitpold Pharmaceuticals, Inc.
P.O. Box 9001
Shirley, NY 11967
1-800-645-1706
www.luitpold.com

1.4. Emergency Telephone Number
Emergency Number: CHEMTREC 1-800-424-9300

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture
Classification (GHS-US)
Not classified

2.2. Label Elements
GHS-US Labeling
No labeling applicable

2.3. Other Hazards
Exposure may aggravate those with pre-existing eye, skin, or respiratory conditions. Refer to patient insert for more information.

2.4. Unknown Acute Toxicity (GHS-US)
25 % of the mixture consists of ingredient(s) of unknown acute toxicity (Oral, Dermal, Inhalation)

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance
Not applicable

3.2. Mixture

<table>
<thead>
<tr>
<th>Name</th>
<th>Product Identifier</th>
<th>%</th>
<th>Classification (GHS-US)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water for injection</td>
<td>(CAS No) 7732-18-5</td>
<td>75</td>
<td>Not classified</td>
</tr>
<tr>
<td>Polysulfated glycosaminoglycan</td>
<td>(CAS No) 64082-61-7</td>
<td>25</td>
<td>Not classified</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>(CAS No) 1310-73-2</td>
<td></td>
<td>Used to adjust pH</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Met. Corr. 1, H290</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Skin Corr. 1A, H314</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Eye Dam. 1, H318</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Aquatic Acute 3, H402</td>
</tr>
<tr>
<td>Hydrochloric acid</td>
<td>(CAS No) 7647-01-0</td>
<td></td>
<td>Used to adjust pH</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Met. Corr. 1, H290</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Acute Tox. 3 (Inhalation:gas), H331</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Skin Corr. 1A, H314</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Eye Dam. 1, H318</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>STOT SE 3, H335</td>
</tr>
</tbody>
</table>

Full text of H-phrases: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of First Aid Measures
First-aid Measures General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible). In the event of accidental injection, immediately call a poison center or seek medical advice.

First-aid Measures After Inhalation: When symptoms occur: go into open air and ventilate suspected area. Seek medical attention.

First-aid Measures After Skin Contact: Remove contaminated clothing. Flush with copious quantities of water for 15 minutes. Seek medical advice.
First-aid Measures After Eye Contact: Immediately flush eyes thoroughly with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Seek medical attention.

First-aid Measures After Ingestion: Rinse mouth. Do NOT induce vomiting.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/Injuries: Not expected to present a significant hazard under anticipated conditions of normal use. Please refer to the package insert for more detailed information.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If you feel unwell, seek medical advice (show the label where possible).

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Water spray, dry chemical, foam, carbon dioxide.

Unsuitable Extinguishing Media: A heavy water stream may spread burning liquid. CAUTION: Carbon dioxide is an asphyxiant. Lack of oxygen can be fatal.

5.2. Special Hazards Arising From the Substance or Mixture

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Firefighting Instructions: Exercise caution when fighting any chemical fire. Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Firefighters must use full bunker gear including NIOSH-approved positive-pressure self-contained breathing apparatus to protect against potential hazardous combustion and decomposition products.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Avoid all unnecessary exposure. Do not breathe vapor or mist.

6.1.1. For Non-emergency Personnel

Protective Equipment: Use appropriate personal protection equipment (PPE). Refer to section 8.2.


6.1.2. For Emergency Responders

Protective Equipment: Equip cleanup crew with proper protection. For further information refer to section 8: "Exposure controls/personal protection."

Emergency Procedures: Ventilate area.

6.2. Environmental Precautions Prevent entry to sewers and public waters.

6.3. Methods and Material for Containment and Cleaning Up

Methods for Cleaning Up: Vacuum spillage with a vacuum cleaner having a high efficiency particulate (HEPA) filter, or absorb liquid with clay absorbent, absorbent pads or paper towels. Use plastic tools to scoop up, sweep or containerize spilled material. Use plastic drums to contain spilled materials. Wipe working surfaces to dryness, and then wash with soap and water.

6.4. Reference to Other Sections See heading 8, Exposure Controls and Personal Protection.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking, or smoking and again when leaving work.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Store in original container. Store in a dry, cool and well-ventilated place.


7.3. Specific End Use(s) For the intra-articular treatment of non-infectious degenerative and/or traumatic joint dysfunction and associated lameness of the carpal joint in horses.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), NIOSH (REL), or OSHA (PEL).

<table>
<thead>
<tr>
<th>Substance</th>
<th>ACGIH Ceiling (mg/m³)</th>
<th>NIOSH REL (ceiling) (mg/m³)</th>
<th>US IDLH (mg/m³)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium hydroxide</td>
<td>2 mg/m³</td>
<td>2 mg/m³</td>
<td>10 mg/m³</td>
</tr>
</tbody>
</table>
Adequan® I.A.
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According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

<table>
<thead>
<tr>
<th>USA OSHA</th>
<th>OSHA PEL (TWA) (mg/m³)</th>
<th>2 mg/m³</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrogen chloride (7647-01-0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>USA ACGIH</td>
<td>ACGIH Ceiling (ppm)</td>
<td>2 ppm</td>
</tr>
<tr>
<td>USA NIOSH</td>
<td>NIOSH REL (ceiling) (mg/m³)</td>
<td>7 mg/m³</td>
</tr>
<tr>
<td>USA NIOSH</td>
<td>NIOSH REL (ceiling) (ppm)</td>
<td>5 ppm</td>
</tr>
<tr>
<td>USA IDLH</td>
<td>US IDLH (ppm)</td>
<td>50 ppm</td>
</tr>
<tr>
<td>USA OSHA</td>
<td>OSHA PEL (Ceiling) (mg/m³)</td>
<td>7 mg/m³</td>
</tr>
<tr>
<td>USA OSHA</td>
<td>OSHA PEL (Ceiling) (ppm)</td>
<td>5 ppm</td>
</tr>
</tbody>
</table>

8.2. Exposure Controls
- Appropriate Engineering Controls: Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

- Personal Protective Equipment
  - Hand Protection: Wear chemically resistant protective gloves.
  - Eye Protection: Chemical goggles or safety glasses.
  - Skin and Body Protection: Wear suitable protective clothing. Wash contaminated clothing before reuse.
  - Respiratory Protection: In case of inadequate ventilation wear respiratory protection.
  - Other Information: When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES
9.1. Information on Basic Physical and Chemical Properties
- Physical State: Liquid
- Appearance: Colorless to slightly yellow
- Odor: Odorless
- Odor Threshold: No data available
- pH: 5 - 6.5
- Evaporation Rate: No data available
- Melting Point: No data available
- Freezing Point: No data available
- Boiling Point: ≈ 100 °C (212 °F)
- Flash Point: No data available
- Auto-ignition Temperature: No data available
- Decomposition Temperature: Not applicable
- Flammability (solid, gas): No data available
- Vapor Pressure: No data available
- Relative Vapor Density at 20 °C: No data available
- Relative Density: No data available
- Specific Gravity: ≈ 1.1
- Solubility: Soluble in water
- Partition Coefficient: N-Octanol/Water: No data available
- Viscosity: No data available

9.2. Other Information: No additional information available

SECTION 10: STABILITY AND REACTIVITY
10.1. Reactivity: Hazardous reactions will not occur under normal conditions.
10.2. Chemical Stability: Stable under recommended handling and storage conditions (see section 7).
10.3. Possibility of Hazardous Reactions: Hazardous polymerization will not occur.
10.4. Conditions to Avoid: Direct sunlight. Extremely high or low temperatures.
10.6. Hazardous Decomposition Products: None known.

SECTION 11: TOXICOLOGICAL INFORMATION
11.1. Information On Toxicological Effects
- Acute Toxicity: Not classified
**Adequan® I.A.**

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<table>
<thead>
<tr>
<th>Substance</th>
<th>Oral Rat LD50</th>
<th>Dermal Rabbit LD50</th>
<th>Inhalation Rat LC50 (1 h)</th>
<th>Inhalation Rat LC50 (4 h)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrogen chloride (7647-01-0)</td>
<td>238 - 277 mg/kg</td>
<td>&gt; 5010 mg/kg</td>
<td>1.68 mg/l</td>
<td>781 ppm/4h (reported as 3124 ppm/1 h)</td>
</tr>
</tbody>
</table>

**Skin Corrosion/Irritation:** Not classified (pH: 5 - 6.5)

**Serious Eye Damage/Irritation:** Not classified (pH: 5 - 6.5)

**Respiratory or Skin Sensitization:** Not classified

**Germ Cell Mutagenicity:** Not classified

**Carcinogenicity:** Not classified

**Hydrogen chloride (7647-01-0)**

<table>
<thead>
<tr>
<th>IARC group</th>
<th>3</th>
</tr>
</thead>
</table>

**Reproductive Toxicity:** Not classified

**Specific Target Organ Toxicity (Single Exposure):** Not classified

**Specific Target Organ Toxicity (Repeated Exposure):** Not classified

**Aspiration Hazard:** Not classified

**SECTION 12: ECOLOGICAL INFORMATION**

12.1. **Toxicity**

**Sodium hydroxide (1310-73-2)**

<table>
<thead>
<tr>
<th>Test</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC50 Fish 1</td>
<td>45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])</td>
</tr>
<tr>
<td>EC50 Daphnia 1</td>
<td>40 mg/l</td>
</tr>
</tbody>
</table>

12.2. **Persistence and Degradability**

- Not established

12.3. **Bioaccumulative Potential**

**Adequan® I.A.**

<table>
<thead>
<tr>
<th>Test</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bioaccumulative Potential</td>
<td>Not established</td>
</tr>
</tbody>
</table>

12.4. **Mobility in Soil**

- No additional information available

12.5. **Other Adverse Effects**

- Other Information: Avoid release to the environment.

**SECTION 13: DISPOSAL CONSIDERATIONS**

13.1. **Waste treatment methods**

- Sewage Disposal Recommendations: Do not empty into drains; dispose of this material and its container in a safe way.

- Waste Disposal Recommendations: Dispose of waste material in accordance with all local, regional, national, and international regulations.

**SECTION 14: TRANSPORT INFORMATION**

14.1. **In Accordance with DOT**

- Not regulated for transport

14.2. **In Accordance with IMDG**

- Not regulated for transport

14.3. **In Accordance with IATA**

- Not regulated for transport

**SECTION 15: REGULATORY INFORMATION**

15.1 **US Federal Regulations**

- Water (7732-18-5)
  - Listed on the United States TSCA (Toxic Substances Control Act) inventory

- Sodium hydroxide (1310-73-2)
  - Listed on the United States TSCA (Toxic Substances Control Act) inventory

- Hydrogen chloride (7647-01-0)
  - Listed on the United States TSCA (Toxic Substances Control Act) inventory
  - Listed on the United States SARA Section 302
  - Listed on United States SARA Section 313

**SARA Section 302 Threshold Planning Quantity (TPQ)**

- 500 (gas only)

**SARA Section 313 - Emission Reporting**

- 1.0 % (acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size)

15.2 **US State Regulations**

- Sodium hydroxide (1310-73-2)
  - U.S. - Massachusetts - Right To Know List
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| U.S. - New Jersey - Right to Know Hazardous Substance List |
| U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List |
| U.S. - Pennsylvania - RTK (Right to Know) List |

**Hydrogen chloride (7647-01-0)**

| U.S. - Massachusetts - Right To Know List |
| U.S. - New Jersey - Right to Know Hazardous Substance List |
| U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List |
| U.S. - Pennsylvania - RTK (Right to Know) List |

**SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION**

| Revision Date | 03/27/2018 |
| Other Information | This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200. |

**GHS Full Text Phrases:**

| Acute Tox. 3 (Inhalation:gas) | Acute toxicity (inhalation:gas) Category 3 |
| Aquatic Acute 3 | Hazardous to the aquatic environment - Acute Hazard Category 3 |
| Eye Dam. 1 | Serious eye damage/eye irritation Category 1 |
| Met. Corr. 1 | Corrosive to metals Category 1 |
| Skin Corr. 1A | Skin corrosion/irritation Category 1A |
| STOT SE 3 | Specific target organ toxicity (single exposure) Category 3 |
| H290 | May be corrosive to metals |
| H314 | Causes severe skin burns and eye damage |
| H318 | Causes serious eye damage |
| H331 | Toxic if inhaled |
| H335 | May cause respiratory irritation |
| H402 | Harmful to aquatic life |

Refer to Luitpold/American Regent prescribing information for further information at: http://americanregent.com/AllProducts.aspx

The information above is believed to be accurate and represents the best information currently available to American Regent. The information has not been verified and we cannot, therefore, guarantee its accuracy or completeness or adequacy for all persons and situations or as to the results to be obtained by use of the information. It is the user's obligation to evaluate and use this product safely and to comply with all applicable laws and regulations. WE MAKE NO WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR USE OR ANY OTHER WARRANTY, EXPRESSED OR IMPLIED, WITH RESPECT TO SUCH INFORMATION AND WE ASSUME NO LIABILITY RESULTING FROM ITS USE. Users should make their own investigations to determine the suitability of the information for their own particular purposes. The user assumes all risks from use of the product. In no event shall Luitpold, its subsidiaries, its affiliates and its contractors be liable for any claims, losses or damages of any third party, or for lost profits, or for any special, indirect, incidental, consequential or exemplary damages however arising, even if Luitpold has been advised of the possibility of such damages.

SDS US (GHS HazCom)