1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY UNDERTAKING

PRODUCT IDENTIFIER/TRADE/MATERIAL NAME: ATELVIA® (Risedronate Sodium) TABLET, DELAYED RELEASE
Containing 35 mg Risedronate Sodium

DESCRIPTION: Risedronate Sodium Tablets
PRODUCT USE: Human Pharmaceutical
USES ADVISED AGAINST: Non-Pharmaceutical Use
CHEMICAL NAME: For Active Ingredient: [1-hydroxy-2-(3-pyridinyl)ethylidene]bis[phosphonic acid] monosodium salt
CHEMICAL FAMILY: For Active Ingredient: Bisphosphonate
HOW SUPPLIED: 35 mg Risedronate Sodium
OTHER DESIGNATIONS: 35 mg Yellow Oval Tablet: NDC:0430-0979-03; NDC:0430-0979-95
FORMULA: For Active Ingredient: Risedronate Sodium: C7H10NO7P2Na•2.5 H2O

SUPPLIER OF THE SAFETY DATA SHEET

RESPONSIBLE PARTY U.S.: ACTAVIS, INC.
U.S. ADDRESS: 400 Interpace Parkway, Morris Corporate Center III
Parsippany, NJ 07054, USA
U.S. BUSINESS PHONE/GENERAL SDS INFORMATION +1-800-272-5525

RESPONSIBLE PARTY EUROPE:
EUROPEAN ADDRESS: 
EUROPEAN BUSINESS PHONE:
EMERGENCY PHONE (U.S./NORTH AMERICA): CHEMTREC: 1-800-424-9300 (24 hours) U.S., Canada, Puerto Rico
EMERGENCY PHONE (OUTSIDE U.S.): CHEMTREC: +1-703-527-3887 (24 hours) Outside North America
Email: SDS@Actavis.com

NOTE: ALL United States Occupational Safety and Health Administration Standard (29 CFR 1910.1200), U.S. State equivalent Standards, Canadian WHMIS [Controlled Products Regulations], EU Directives through EC 1907: 2006, and European Union CLP EC 1272/2008, required information is included in appropriate sections based on the U.S. ANSI Z400.1-2010 format. This product has been classified in accordance with the hazard criteria of the countries listed above.

DATE OF PREPARATION: November 30, 2013 DATE OF REVISION: New

2. HAZARDS IDENTIFICATION

EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION: According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.

EMERGENCY OVERVIEW:

Product Description: This product is supplied as yellow, oval tablets.
Health Hazards: In the workplace, exposure via inhalation or eye contact may cause irritation. No information is available on possible effects from skin exposure. Accidental ingestion may be harmful. In therapeutic use, the most common adverse effects reported include back pain, muscle pain, abdominal pain, and upset stomach. Hypersensitivity reactions and sometimes severe effects on the musculoskeletal system have been reported. May cause harm to the fetus during pregnancy and adverse effects on fertility, based on animal information. Other adverse effects seen from therapeutic use are described in Section 11 (Toxicological information).
Flammability Hazards: If heated to high temperatures for a prolonged period, the product may ignite. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including iron, carbon, magnesium, silicon and nitrogen oxides and hydrogen chloride).
Reactivity Hazards: This product is not reactive.
Environmental Hazards: Large quantities of this product released to the aquatic and terrestrial environment may have an adverse effect.
Emergency Considerations: Emergency responders should wear appropriate protection for the situation to which they respond.
3. COMPOSITION and INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>CAS #</th>
<th>EINECS #</th>
<th>% w/w</th>
<th>LABEL ELEMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risedronate Sodium [1-hydroxy-2-(3-pyridinyl)ethylidene] bis[phosphonic acid] monosodium salt</td>
<td>115436-72-1</td>
<td>Not Listed</td>
<td>Proprietary</td>
<td>SELF-CLASSIFICATION&lt;br&gt;EU 67/548&lt;br&gt;Classification: Reproductive Toxicity Cat. 3, Irritant&lt;br&gt;Risk Phrase Codes: R60, R62, R36/38&lt;br&gt;Hazard Symbols: XnXi&lt;br&gt;GHS and EU 1272/2008&lt;br&gt;Classification: Reproductive Toxicity Cat. 2, Acute Oral Toxicity Cat. 5, Skin Irritation Cat. 2, Eye Irritation Cat. 2A&lt;br&gt;Hazard Codes: H361fd, H303, H315, H319&lt;br&gt;Hazard Symbol/Pictogram: GHS07, GHS08</td>
</tr>
</tbody>
</table>

EXCIPIENTS:

<table>
<thead>
<tr>
<th>EXCIPIENT</th>
<th>CAS #</th>
<th>EINECS #</th>
<th>% w/w</th>
<th>LABEL ELEMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Edetate Sodium</td>
<td>6381-02-6</td>
<td>For Anhydrous: 200-449-4</td>
<td>Proprietary</td>
<td>EU (67/548/EEC): No Classification Applicable&lt;br&gt;EU/GHS 1272/2008: No Classification Applicable</td>
</tr>
<tr>
<td>Magnesium Stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>Proprietary</td>
<td>EU (67/548/EEC): No Classification Applicable&lt;br&gt;EU/GHS 1272/2008: No Classification Applicable</td>
</tr>
<tr>
<td>Methacrylic Acid Copolymer Type A</td>
<td>33434-24-1</td>
<td>Not Listed</td>
<td>Proprietary</td>
<td>EU (67/548/EEC): No Classification Applicable&lt;br&gt;EU/GHS 1272/2008: No Classification Applicable</td>
</tr>
<tr>
<td>Silicified Microcrystalline Cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>Proprietary</td>
<td>EU (67/548/EEC): No Classification Applicable&lt;br&gt;EU/GHS 1272/2008: No Classification Applicable</td>
</tr>
<tr>
<td>Simethicone</td>
<td>8050-81-5</td>
<td>Not Listed</td>
<td>Proprietary</td>
<td>EU (67/548/EEC): No Classification Applicable&lt;br&gt;EU/GHS 1272/2008: No Classification Applicable</td>
</tr>
<tr>
<td>Sodium Starch Glycolate</td>
<td>9063-38-1</td>
<td>Not Listed</td>
<td>Proprietary</td>
<td>EU (67/548/EEC): No Classification Applicable&lt;br&gt;EU/GHS 1272/2008: No Classification Applicable</td>
</tr>
<tr>
<td>Stearic Acid</td>
<td>57-11-4</td>
<td>200-313-4</td>
<td>Proprietary</td>
<td>SELF CLASSIFICATION&lt;br&gt;EU 67/548&lt;br&gt;Classification: Not Applicable&lt;br&gt;Risk Phrases: Not Applicable&lt;br&gt;Hazard Symbol: Not Applicable&lt;br&gt;EU/GHS 1272/2008&lt;br&gt;Classification: Acute Oral Toxicity Cat. 5, Acute Dermal Toxicity Cat. 5&lt;br&gt;Hazard Statement Codes: H303 + H313&lt;br&gt;Hazard Symbol/Pictogram: None Applicable</td>
</tr>
<tr>
<td>Talc</td>
<td>14807-96-6</td>
<td>238-877-9</td>
<td>Proprietary</td>
<td>EU (67/548/EEC): No Classification Applicable&lt;br&gt;EU/GHS 1272/2008: No Classification Applicable</td>
</tr>
<tr>
<td>Triethyl Citrate</td>
<td>77-93-0</td>
<td>201-070-7</td>
<td>Proprietary</td>
<td>SELF CLASSIFICATION&lt;br&gt;EU 67/548&lt;br&gt;Classification: Harmful&lt;br&gt;Risk Phrases: R20&lt;br&gt;Hazard Symbol: Xn&lt;br&gt;EU/GHS 1272/2008&lt;br&gt;Classification: Acute Inhalation Toxicity Cat. 4&lt;br&gt;Hazard Statement Codes: H332&lt;br&gt;Hazard Symbol/Pictogram: GHS07</td>
</tr>
</tbody>
</table>

See Section 16 for full classification information of product and components.

4 FIRST-AID MEASURES

PROTECTION OF FIRST AID RESPONDERS: First-aid responders should not attempt to treat victims of exposure to this material without adequate personal protective equipment. Rescuers should be taken for medical attention, if necessary.

DESCRIPTION OF FIRST AID MEASURES: Victim(s) must be taken for medical attention. Remove victim(s) to fresh air, as quickly as possible. Only trained personnel should administer supplemental oxygen and/or cardio-pulmonary resuscitation, when necessary. Take copy of label and SDS to physician or other health professional with victim(s).

Inhalation: If dusts or particulates from this product are inhaled, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention if adverse effect occurs after removal to fresh air.

Skin Exposure: If the product contaminates the skin and adverse effect occurs, begin decontamination with running water. Minimum flushing is for 20 minutes. Do not interrupt flushing. Remove exposed or contaminated clothing, taking care not to contaminate eyes. Seek medical attention if adverse effect occurs after flushing.

Eye Exposure: If particulates from this product enter the eyes, open victim's eyes while under gently running water. Use sufficient force to open eyelids. Have victim "roll" eyes. Minimum flushing is for 20 minutes. Do not interrupt flushing. Seek immediate medical attention after flushing if adverse effect occurs.

Ingestion Exposure: If this product is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, do not induce vomiting. Rinse mouth with water immediately. Victim should drink large quantities of water. If milk is available, victim should drink it after drinking water. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or unable to swallow.

IMPORTANT SYMPTOMS AND EFFECTS: See Sections 2 (Hazard Identification) and 11 (Toxicological Information).
### 4 FIRST-AID MEASURES (Continued)

**MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:** In therapeutic use, pre-existing renal impairment, esophagus abnormalities, mobility problems, Paget’s disease, osteonecrosis of the jaw (ONJ), glucocorticoid-induced osteoporosis, low calcium or phosphorus conditions and asthma may be aggravated. Workplace exposure may also aggravate these conditions. Persons who may have hypersensitivity reactions to any ingredient or other disorders described in Section 11 (Toxicological Information) may experience aggravation upon exposure.

**IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED:** Treat symptoms and eliminate exposure. Persons developing hypersensitivity reactions should receive immediate medical attention. No specific antidote is known. Gastric lavage may be considered to remove unabsorbed drug. Standard procedures that are effective for treating hypocalcemia, including the administration of calcium intravenously, would be expected to restore physiologic amounts of ionized calcium and to relieve signs and symptoms of hypocalcemia.

### 5. FIRE-FIGHTING MEASURES

**FLASH POINT:** Not established.

**AUTOIGNITION TEMPERATURE:** Not established.

**FLAMMABLE LIMITS & METHOD OF DETERMINATION (in air by volume, %):** Not determined.

**FIRE EXTINGUISHING MEDIA:** Use extinguishing media appropriate for surrounding fire.

**UNSUITABLE EXTINGUISHING MEDIA:** None known.

**SPECIFIC HAZARDS ARISING FROM THE CHEMICAL:** This product may ignite if highly heated for a prolonged period of time. When involved in a fire, the products of thermal decomposition may include irritating fumes and toxic gases (e.g., iron, carbon, magnesium, silicon and nitrogen oxides and hydrogen chloride).

- Explosion Sensitivity to Static Discharge: Not sensitive.

**SPECIAL PROTECTIVE ACTIONS FOR FIRE-FIGHTERS:** Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus (SCBA) and full protective equipment. Contaminated protective equipment should be thoroughly washed with running water prior to removal of SCBA respiratory protection. Firefighters whose protective equipment becomes contaminated should thoroughly shower with warm, soapy water and should receive medical evaluation if they experience any adverse effects.

### 6. ACCIDENTAL RELEASE MEASURES

**PERSONAL PRECAUTIONS:** In the event of a spill, clear the area and protect people.

**PROTECTIVE EQUIPMENT:**

- **Small Spills:** For incidental spills (e.g., 1 vial of tablets), wear double latex or nitrile disposable gloves and eye protection.
- **Large Spills:** For large spills (e.g., a pallet of vials), protective apparel should be used with a respirator when there is any danger of airborne dusts being generated. Minimum Personal Protective Equipment should be rubber gloves, rubber boots, face shield, and Tyvek suit.

**METHODS FOR CLEANUP AND CONTAINMENT:**

- **Small Spills:** Pick-up or sweep-up spilled tablets.
- **Large Spills:** Trained personnel following pre-planned procedures should handle non-incidental releases. Access to the spill areas should be restricted. Sweep up spilled product carefully, avoiding the generation of airborne dusts. Decontaminate the area of the spill thoroughly using detergent and water. Place all spill residue in an appropriate container and seal. Move to a secure area. Do not mix with wastes from other materials. If necessary, discard contaminated response equipment or rinse with soapy water before returning such equipment to service. Dispose of in accordance with applicable international, national, state, and local procedures (see Section 13, Disposal Considerations).

**ENVIRONMENTAL PRECAUTIONS:** Prevent material from entering sewer or confined spaces, waterways, soil or public waters. Do not flush to sewer. For spills on water, contain, minimize dispersion and collect.

### 7. HANDLING and USE

**PRECAUTIONS FOR SAFE HANDLING:** Employees must be trained to properly use this compound. Particular care in working with this material must be practiced in pharmacies and other preparation areas, during manufacture of pharmaceutical preparations, and during patient administration. Use of this compound should be performed in a designated area for working with narcotic compounds. As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat, drink, smoke, or apply cosmetics in work areas where this product is handled or stored. Wash thoroughly after handling this product or equipment and containers of this product. Follow SPECIFIC USE INSTRUCTIONS supplied with this product. Use of this product should be performed in a designated area for working with drugs. Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this product, and during patient administration. If necessary, work areas must be regularly cleaned and decontaminated.

**PRODUCT PREPARATION INSTRUCTIONS FOR MEDICAL PERSONNEL:** Handle this material following standard medical practices and following the recommendations presented on the Package Insert.
7. HANDLING and USE (Continued)

CONDITIONS FOR SAFE STORAGE: Containers of this product must be properly labeled. Store this product in original container. Store at 20°C to 25°C (68°F to 77°F). (See USP Controlled Room Temperature.) Inspect bottles containing this product for leaks or damage. Store away from incompatible materials (see Section 10, Stability and Reactivity).

SPECIFIC END USE(S): This product human pharmaceutical. Follow all industry standards for use of this product.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

EXPOSURE LIMITS/CONTROL PARAMETERS:

Ventilation and Engineering Controls: Use with adequate ventilation. Follow standard medical product handling procedures. During decontamination of work surfaces, workers should wear the same equipment recommended in Section 6 (Accidental Release Measures) of this SDS.

Occupational/Workplace Exposure Limits/Guidelines:

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>CAS #</th>
<th>ACSHNL/TLVs</th>
<th>OSHA-PELs</th>
<th>NIOSH-RELs</th>
<th>NIOSH</th>
<th>OTHER</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>TWA mg/m³</td>
<td>STEL mg/m³</td>
<td>TWA mg/m³</td>
<td>STEL mg/m³</td>
<td>IDLH mg/m³</td>
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<tr>
<td>Risedronate Sodium</td>
<td>115436-72-1</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
</tr>
<tr>
<td>Edetate Sodium</td>
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<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
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<tr>
<td>Ferric Oxide Yellow</td>
<td>20344-49-4</td>
<td>5 (resp.</td>
<td>NE</td>
<td>10 (fume)</td>
<td>NE</td>
<td>5 (dusts &amp;</td>
</tr>
<tr>
<td>(continued)</td>
<td></td>
<td>fract.)</td>
<td></td>
<td></td>
<td></td>
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<td>10 NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
</tr>
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<td>33434-24-1</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
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<td>NE</td>
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<td>NE</td>
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<td>10 NE</td>
<td>15 (total</td>
<td>10 (total</td>
<td>NE</td>
<td>10 (total</td>
</tr>
<tr>
<td>(continued)</td>
<td></td>
<td></td>
<td>dust)</td>
<td>dust)</td>
<td></td>
<td>dust) (respirable) fraction</td>
</tr>
<tr>
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<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
</tr>
<tr>
<td>Sodium Starch Glycollate</td>
<td>9063-38-1</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
</tr>
<tr>
<td>Stearic Acid</td>
<td>57-11-4</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
</tr>
<tr>
<td>Talc</td>
<td>14807-96-6</td>
<td>2 (resp.</td>
<td>NE</td>
<td>20 mppcf</td>
<td>NE</td>
<td>2 (respirable</td>
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<tr>
<td>(continued)</td>
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<td>fract.)</td>
<td></td>
<td>(containing &lt; 1% quartz)</td>
<td></td>
<td>dust) and &lt; 1% quartz</td>
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<tr>
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<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
</tr>
</tbody>
</table>

International Occupational Exposure Limits: In addition to the exposure limit values cited in this section, other exposure limits have been established by various countries for the components of this product. The exposure limits given may not be the most current; individual country authorities should be contacted to check on more current limits.

IRON OXIDES:
- ARAB Republic of Egypt: TWA = 3 ppm (5 mg/m³) (fume), JAN 1993
- Australia: TWA = 0.1 mg(Fe)/m³, JUL 2008
- Australia: TWA = 5 mg(Fe)/m³ (fume), JUL 2008
- Belgium: TWA = 2 ppm (5 mg(Fe)/m³) (fume), MAR 2002
- Denmark: TWA = 3.5 mg(Fe)/m³, OCT 2002
- Finland: TWA = 5 mg(Fe)/m³, fume, SEP 2009
- France: VME = 5 mg(Fe)/m³ (fume), FEB 2006
- Germany: MAK = 1.5 mg(Fe)/m³ (respirable), 2005
- Hungary: TWA = 6 mg/m³ (resp), SEP 2000
- Japan: OEL = 1 mg/m³ (resp), 4 mg/m³ (total), APR 2007
- Korea: TWA = 10 mg/m³, 2006
- Korea: TWA = 5 mg/m³, 2006
- Mexico: TWA = 10 mg/m³, STEL = 20 mg/m³, 2004
- The Netherlands: MAC-TGG = 5 mg(Fe)/m³, 2003
- The Netherlands: MAC-TGG = 10 mg/m³, 2003
- New Zealand: TWA = 5 mg(Fe)/m³ (dust and fume), JAN 2002
- New Zealand: TWA = 10 mg/m³ (inspirable dust), JAN 2002
- Norway: TWA = 3 mg/m³, JAN 1999
- The Philippines: TWA = 10 mg/m³ (fume), JAN 1993
- Poland: MAC(TWA) fume = 5 mg/m³, MAC(STEL) = 10 mg/m³

IRON OXIDES (continued):
- Russia: TWA = 6 mg/m³, JUN 2003
- Sweden: TWA = 3.5 mg(Fe)/m³ (resp. dust), JUN 2005
- Switzerland: MAK-W = 3 mg/m³, DEC 2006
- Thailand: TWA = 10 mg/m³ (fume), JAN 1993
- Turkey: TWA = 10 mg/m³ (fume), JUN 2000
- United Kingdom: TWA = 4 mg/m³ (resp), 2005
- United Kingdom: TWA = 10 mg/m³ (inspirable), 2005
- United Kingdom: TWA = 5 mg(Fe)/m³, STEL = 10 mg(Fe)/m³, 2005
- In Argentina, Bulgaria, Colombia, Jordan, Singapore, Vietnam, check ACGIH TLV

MAGNESIUM STEARATE:
- New Zealand: TWA = 10 mg/m³ (inspirable dust), JAN 2002
- Sweden: TWA = 5 mg/m³, JUN 2005
- Belgium: TWA = 10 mg/m³, MAR 2002
- Silicified Microcrystalline Cellulose (continued):
- Belgium: TWA = 10 mg/m³, MAR 2002
- France: VME = 5 mg(Fe)/m³ (fume), FEB 2006
- Germany: MAK = 1.5 mg(Fe)/m³ (respirable), 2005
- Hungary: TWA = 6 mg/m³ (resp), SEP 2000
- Japan: OEL = 1 mg(m³) (resp), 4 mg/m³ (total), APR 2007
- Korea: TWA = 10 mg/m³, 2006
- Korea: TWA = 5 mg/m³, 2006
- Mexico: TWA = 10 mg/m³, STEL = 20 mg/m³, 2004
- The Netherlands: MAC-TGG = 5 mg(Fe)/m³, 2003
- The Netherlands: MAC-TGG = 10 mg/m³, 2003
- New Zealand: TWA = 5 mg(Fe)/m³ (dust and fume), JAN 2002
- New Zealand: TWA = 10 mg/m³ (inspirable dust), JAN 2002
- Norway: TWA = 3 mg/m³, JAN 1999
- The Philippines: TWA = 10 mg/m³ (fume), JAN 1993
- Poland: MAC(TWA) fume = 5 mg/m³, MAC(STEL) = 10 mg/m³

SILICIFIED MICROCRYSTALLINE CELLULOSE:
- Belgium: TWA = 10 mg/m³, MAR 2002
- France: VME = 5 mg(Fe)/m³, FEB 2006
- Korea: TWA = 10 mg/m³, 2006
- Mexico: TWA = 10 mg/m³, STEL = 20 mg/m³, 2004
- The Netherlands: MAC-TGG = 2 mg/m³, 2003
- New Zealand: TWA = 10 mg/m³ (inspirable dust), JAN 2002
- Russia: STEL = 10 mg/m³, JUN 2003
- Switzerland: MAK-W = 6 mg/m³, DEC 2006
- United Kingdom: TWA = 10 mg/m³ (inspirable), 2005
- United Kingdom: TWA = 4 mg/m³, STEL = 20 mg/m³ (respirable), 2005
- In Argentina, Bulgaria, Colombia, Jordan, Singapore, Vietnam, check ACGIH TLV

8. EXPOSURE CONTROLS - PERSONAL PROTECTION (Continued)

PERSONAL PROTECTIVE EQUIPMENT (continued):

Respiratory Protection: Respiratory protection is generally not needed during routine conditions of use of this product. If respiratory protection is needed, use only respiratory protection authorized under appropriate regional regulations.

Eye Protection: No eye protection is normally needed during medical administration of this product. During operations in which dusts of the product may be generated, splash goggles or safety glasses should be considered.

Hand Protection: During medical administration of this product, medical latex or nitrile gloves should be worn to avoid absorption of the product. During manufacture or other similar industrial operations, wear the appropriate hand protection for the process. Use double gloves for spill response, as stated in Section 6 (Accidental Release Measures) of this SDS.

Body Protection: Use appropriate protective clothing for the task (e.g., lab coat, etc.)

9. PHYSICAL and CHEMICAL PROPERTIES

The following information is for the product.

**FORM:** Oval tablets.

**ODOR:** Odorless.

**COLOR:** Yellow.

**HOW TO DETECT THIS SUBSTANCE (identification properties):** The appearance of this product is a distinguishing characteristic.

The following values are available for the active ingredient, Risedronate Sodium:

**FORM:** Crystalline solid.

**MOLECULAR FORMULA:** C_{7}H_{10}NO_{7}P_{2}Na•2.5 H_{2}O

**MOLAR MASS:** 350.13

**ODOR:** White to off-white.

**COLOR:** Yellow.

**ODOR THRESHOLD:** Not applicable.

**DECOMPOSITION PRODUCTS:** None known.

**CHEMICAL STABILITY:** This product is not reactive.

**DECOMPOSITION PRODUCTS:** Combustion: If exposed to extremely high temperatures, the products of thermal decomposition may include irritating fumes and toxic gases (e.g. iron, carbon, magnesium, silicon and nitrogen oxides and hydrogen chloride). Hydrolysis: None known.

**MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE:** This product is generally compatible with other common materials in a medical facility. Acids and alkalies, and other chemicals that could affect its performance should be avoided.

**POSSIBILITY HAZARDOUS REACTION/POLYMERIZATION:** Will not occur.

**CONDITIONS TO AVOID:** Avoid heat, light, and contact with incompatible chemicals.

10. STABILITY and REACTIVITY

**CHEMICAL STABILITY:** This product is not reactive.

**DECOMPOSITION PRODUCTS:** Combustion: If exposed to extremely high temperatures, the products of thermal decomposition may include irritating fumes and toxic gases (e.g. iron, carbon, magnesium, silicon and nitrogen oxides and hydrogen chloride). Hydrolysis: None known.

**MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE:** This product is generally compatible with other common materials in a medical facility. Acids and alkalies, and other chemicals that could affect its performance should be avoided.

**POSSIBILITY HAZARDOUS REACTION/POLYMERIZATION:** Will not occur.

**CONDITIONS TO AVOID:** Avoid heat, light, and contact with incompatible chemicals.

11. TOXICOLOGICAL INFORMATION

**SYMPTOMS OF EXPOSURE BY ROUTE OF EXPOSURE:** The health hazard information provided below is pertinent to medical employees using this product in an occupational setting. The following paragraphs describe the symptoms of exposure by route of exposure.

**Inhalation:** Inhalation of airborne dusts generated from the drug product may slightly irritate the nose, throat, and lungs. Inhalation of large amounts may also cause under ‘Other Potential Health Effects’.

**Contact with Skin or Eyes:** Acute skin contact is not expected to cause adverse effect. Prolonged or repeated skin contact may cause dermatitis (dry, red skin). Contact with the eyes of airborne dusts generated by damaged tablets of this product may cause mild to moderate irritation, redness, and tearing.

**Skin Absorption:** No information available.

**Ingestion:** Ingestion is not a significant route of occupational overexposure. Acute ingestion of large quantities of this product caused by poor hygiene practices may be harmful. Symptoms of prolonged or repeated ingestion, as may occur when poor industrial hygiene is practiced, may include those described for ‘Other Potential Health Effects’.

**Injection:** Injection is not a likely route of exposure for the form of this product.

**OTHER POTENTIAL HEALTH EFFECTS-Therapeutic Doses:** In therapeutic use, the most common adverse effects reported include back pain, muscle pain, abdominal pain, and upset stomach. Hypersensitivity reactions and sometimes severe effects on the musculoskeletal system have been reported. May cause harm to the fetus during pregnancy and adverse effects on fertility, based on animal information.
The following excipient ingredients are listed:

- **IRON OXIDES** (based on CAS#: 1309-37-1): ACGIH TLV-A4 (Not Classifiable as a Human Carcinogen); IARC-3 (Unclassifiable as to Carcinogenicity in Humans); MAK-3B [respirable fraction] (Substances for Which in vitro tests or animal studies have yielded evidence of carcinogenic effects that is not sufficient for classification of the substance in one of the other categories.)

- **MAGNESIUM STEARATE** (as a stearate compound): ACGIH TLV-A4 (Not Classifiable as Human Carcinogen); IARC-3 (Unclassifiable as to Carcinogenicity in Humans); MAK-3B [respirable fraction] (Substances for Which Could Be Carcinogenic for Man but Cannot Be Assessed Conclusively Because of Lack of Data. Substances for which in vitro tests or animal studies have yielded evidence of carcinogenic effects that is not sufficient for classification of the substance in one of the other categories.)
CARCINOGENIC POTENTIAL OF COMPONENTS (continued): The remaining components of this product are not found on the following lists: U.S. EPA, U.S. NTP, U.S. OSHA, U.S. NIOSH, GERMAN MAK, IARC, or ACGIH and therefore are neither considered to be nor suspected to be cancer-causing agents by these agencies.

REPRODUCTIVE TOXICITY INFORMATION: There are no adequate and well-controlled studies of this product or Risedronate Sodium in pregnant women; this product may cause fetal harm when administered to a pregnant woman. In the workplace, the risk to the fetus should be communicated and the appropriate action should be taken to prevent exposure in accordance with company policy and regulatory requirements. Bisphosphonates are incorporated into the bone matrix, from which they are gradually released over periods of weeks to years. The amount of bisphosphonate incorporation into adult bone, and hence, the amount available for release back into the systemic circulation, is directly related to the dose and duration of bisphosphonate use. There are no data on fetal risk in humans. However, there is a theoretical risk of fetal harm, predominantly skeletal, if a woman becomes pregnant after completing a course of bisphosphonate therapy. The impact of variables such as time between cessation of bisphosphonate therapy to conception, the particular bisphosphonate used, and the route of administration (intravenous versus oral) on this risk has not been studied. This product is rated by the FDA for therapeutic risk as Pregnancy Risk Category C (Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks).

Mutagenicity: Risedronate did not exhibit genetic toxicity in the following assays: In vitro bacterial mutagenesis in Salmonella and E. coli (Ames assay), mammalian cell mutagenesis in CHO/HGPRT assay, unscheduled DNA synthesis in rat hepatocytes and an assessment of chromosomal aberrations in vivo in rat bone marrow. Risedronate was positive in a chromosomal aberration assay in CHO cells at highly cytotoxic concentrations (greater than 675 mcg/mL, survival of 6% to 7%). When the assay was repeated at doses exhibiting appropriate cell survival (29%), there was no evidence of chromosomal damage.

Embryotoxicity/Teratogenicity: In animal studies, pregnant rats received Risedronate Sodium during organogenesis at doses 1 to 26 times the human dose of 30 mg/day. Survival of neonates was decreased in rats treated during gestation with oral doses approximately 5 times the human dose and body weight was decreased in neonates from dams treated with approximately 26 times the human dose. The number of fetuses exhibiting incomplete ossification of sternebrae or skull from dams treated with approximately 2.5 times the human dose was significantly increased compared to controls. Both incomplete ossification and unossified sternebrae were increased in rats treated with oral doses approximately 5 times the human dose. A low incidence of cleft palate was observed in fetuses from female rats treated with oral doses approximately equal to the human dose. The relevance of this finding to human use of Atelvia is unclear. No significant fetal ossification effects were seen in rabbits treated with oral doses approximately 7 times the human dose (the highest dose tested). However, 1 of 14 litters were aborted and 1 of 14 litters were delivered prematurely.

Similar to other bisphosphonates, treatment during mating and gestation with doses of Risedronate Sodium approximately the same as the 30 mg/day human dose resulted in periparturient hypocalcemia and mortality in pregnant rats allowed to deliver. Dosing multiples provided above are based on the recommended human dose of 30 mg/day and normalized using body surface area (mg/m²). Actual animal doses were 3.2, 7.1 and 16 mg/kg/day in the rat and 10 mg/kg/day in the rabbit.

Reproductive Toxicity: In female rats, ovulation was inhibited at an oral dose approximately 5 times the human dose. Decreased implantation was noted in female rats treated with doses approximately 2.5 times the human dose. In male rats, testicular and epididymal atrophy and inflammation were noted at approximately 13 times the human dose. Testicular atrophy was also noted in male rats after 13 weeks of treatment at oral doses approximately 5 times the human dose. There was moderate-to-severe spermatid maturation block after 13 weeks in male dogs at an oral dose approximately 8 times the human dose. These findings tended to increase in severity with increased dose and exposure time. Dosing multiples provided above are based on the recommended human dose of 30 mg/day and normalized using body surface area (mg/m²). Actual doses were 24 mg/kg/day in rats, 32 mg/kg/day in mice, and 8, 16 and 40 mg/kg/day in dogs. Risedronate was detected in feeding pups exposed to lactating rats for a 24-hour period post-dosing, indicating a small degree of lacteal transfer. It is not known whether Atelvia is excreted in human milk. Because many drugs are excreted in human milk, and because of the potential for serious adverse reactions in nursing infants, nursing mothers should be advised of these effects and the appropriate action should be taken to prevent exposure.

ACGIH BIOLOGICAL EXPOSURE INDICES (BEIs): Currently, ACGIH Biological Exposure Indices (BEIs) have not been determined for the components of this product.

12. ECOLOGICAL INFORMATION

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

MOBILITY: This product has not been tested for mobility in soil.

PERSISTENCE AND BIODEGRADABILITY: This product has not been tested for persistence or biodegradability. It is expected that the components will slowly degrade in the environment and form a variety of organic and inorganic materials; however, no specific information is known.

BIO-ACCUMULATION POTENTIAL: This product has not been tested for bio-accumulation potential.

ECOTOXICITY: This product may be harmful to aquatic and terrestrial organisms; all releases to terrestrial, atmospheric and aquatic environments should be avoided. The active ingredient can cause long-term harm to algae and other aquatic organisms.

RISENDRONATE SODIUM (continued):

EC50 (Daphnia magna) 184 mg/L

OTHER ADVERSE EFFECTS: This product does not contain any component with known ozone depletion potential.

ATELVIA® (Risedronate Sodium) TABLET, DELAYED RELEASE SDS

EFFECTIVE DATE: NOVEMBER 30, 2013

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12. ECOLOGICAL INFORMATION (Continued)

RESULTS OF PBT AND vPvB ASSESSMENT: No Data Available. PBT and vPvB assessments are part of the chemical safety report required for some substances in European Union Regulation (EC) 1907/2006, Article 14.

ENVIRONMENTAL EXPOSURE CONTROLS: Controls should be engineered to prevent release to the environment, including procedures to prevent spills, atmospheric release and release to waterways.

13. DISPOSAL CONSIDERATIONS

WASTE TREATMENT/DISPOSAL METHODS: Waste disposal must be in accordance with appropriate Federal, State, and local regulations.

PRECAUTIONS TO BE FOLLOWED DURING WASTE HANDLING: Wear proper protective equipment when handling waste materials.

U.S. EPA WASTE NUMBER: Not applicable to wastes consisting only of this product.

EUROPEAN WASTE CODES: Wastes from Human or Animal Health Care or Related Research: 18 01 08: Medicines Other Than Those Mentioned in 18 01 07.

14. TRANSPORTATION INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION REGULATIONS: This product is not classified as dangerous goods, per U.S. DOT regulations, under 49 CFR 172.101.

TRANSPORT CANADA, TRANSPORTATION OF DANGEROUS GOODS REGULATIONS: This product is not classified as Dangerous Goods, per regulations of Transport Canada.

INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA): This product is not classified as Dangerous Goods, by rules of IATA.

INTERNATIONAL MARITIME ORGANIZATION (IMO) DESIGNATION: This product is not classified as Dangerous Goods by the International Maritime Organization.

EUROPEAN AGREEMENT CONCERNING THE INTERNATIONAL CARRIAGE OF DANGEROUS GOODS BY ROAD (ADR): This product is not classified by the United Nations Economic Commission for Europe to be dangerous goods.

TRANSPORT IN BULK ACCORDING TO THE IBC CODE: Not applicable.

ENVIRONMENTAL HAZARDS: This product does not meet the criteria of environmentally hazardous according to the criteria of the UN Model Regulations (as reflected in the IMDG Code, ADR, RID, and ADN) and not component is specifically listed in Annex III under MARPOL 73/78.

15. REGULATORY INFORMATION

UNITED STATES REGULATIONS:

U.S. SARA Reporting Requirements: The components of this product are not subject to the reporting requirements of Sections 302, 304, and 313 of Title III of the Superfund Amendments and Reauthorization Act.

U.S. SARA Threshold Planning Quantity (TPQ): There are no specific Threshold Planning Quantities for any component of this product. The default Federal SDS submission and inventory requirement filing threshold of 10,000 lb (4,540 kg) therefore applies, per 40 CFR 370.20.

U.S. CERCLA Reportable Quantities (RQ): Not applicable.

U.S. TSCA Inventory Status: This product is regulated under Food and Drug Administration standards; it is not subject to requirements under TSCA.

Other U.S. Federal Regulations: Regulations of the FDA under the Federal Food, Drug and Cosmetic Act are applicable when this material is used in pharmaceutical preparations. Under the Hazard Communication Standard (HCS), Section (b)(5)(ii) drugs are subject to labeling requirements by the FDA under the Federal Food, Drug and Cosmetic Act and are exempt from labeling provisions of the HCS; this section of the HCS exempts only labeling requirements and not requirements for a Safety Data Sheet for drugs.

California Safe Drinking Water and Toxic Enforcement Act (Proposition 65): No component of this product is on the California Proposition 65 Lists.

CANADIAN REGULATIONS:

Canadian DSL Inventory Status: This product regulated by the Therapeutic Products Programme (TPP) of Health Canada and so it excepted from requirements of the DSL/NDSL Inventory.

Canadian Environmental Protection Act (CEPA) Priorities Substances Lists: The components of this product are not on the CEPA Priorities Substances Lists.

Canadian WHMIS Classification and Symbol: The WHMIS Requirements of the Hazardous Products Act does not apply in respect of the advertising, sale or importation of any cosmetic, device, drug or food within the meaning of the Food and Drugs Act.

EUROPEAN REGULATIONS:

Safety, Health, and Environmental Regulations/Legislation Specific for the Product: When formulated in a finished medicinal product for human use, this material is subject to Directive 2001/83/EC and subsequent amendments to the directive.

16. OTHER INFORMATION

ANSI LABELING (Based on 129.1, Provided to Summarize Occupational Exposure Hazards):  WARNING! MAY BE HARMFUL IF ACCIDENTALLY INGESTED. LIMITED EVIDENCE OF HARM TO FETUS AND ADVERSE EFFECTS ON FERTILITY DURING PREGNANCY, BASED ON ANIMAL DATA. CONTAINS COMPOUND THAT CAN CAUSE HARM TO AQUATIC ORGANISMS. COMBUSTIBLE IF EXPOSED TO HIGH TEMPERATURES. Do not take internally without prescription. Avoid unnecessary contact with skin, eyes, and clothing. Wash thoroughly after handling. Wear gloves, goggles, and appropriate body protection during handling or administration. FIRST-AID: In case of contact, flush skin or eyes with plenty of water. If adverse respiratory reaction occurs, give oxygen and seek immediate medical attention. If ingested, DO NOT induce vomiting-seek immediate medical attention. IN CASE OF FIRE: Use water fog, dry chemical, CO2, or “alcohol” foam. IN CASE OF SPILL: Pick up or sweep up spilled product. Place residual in appropriate container and seal. Dispose of according to applicable regulations. Consult Safety Data Sheet for additional information.

GLOBAL HARMONIZATION AND EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION: According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.


CLASSIFICATION OF COMPONENTS:

Risedronate Sodium: This is a self-classification:

Classification: Reproductive Toxicity Category 2, Acute Oral Toxicity Category 5, Eye Skin Irritation Category 2, Irritation Category 2A


Stearic Acid: Self-Classification

Classification: Acute Oral Toxicity Category 5, Acute Dermal Toxicity Category 5

Hazard Statements: H303 + H313: May be harmful if swallowed or in contact with skin.

Triethyl Citrate: Self-Classification

Classification: Acute Inhalation Toxicity Category 4

Hazard Statements: H332: Harmful if inhaled.

All Other Components: An official classification for these substances has not been published nor is applicable.

67/548/EEC:

Risedronate Sodium: This is a self-classification:

Classification: Reproductive Toxicity Category 3, Irritant


Triethyl Citrate: Self-Classification

Classification: Harmful

Risk Phrases: R20: Harmful by inhalation.

All Other Components: An official classification for these substances has not been published nor is applicable.

REFERENCES AND DATA SOURCES: Contact the supplier for information.

METHODS OF EVALUATING INFORMATION FOR THE PURPOSE OF CLASSIFICATION: Bridging principles were used to classify this product.

REVISION DETAILS: New.

This Safety Data Sheet is offered pursuant to OSHA’s Hazard Communication Standard, 29 CFR, 1910.1200. Other government regulations must be reviewed for applicability to this product. To the best of Actavis, Inc. knowledge, the information contained herein is reliable and accurate as of this date, however, accuracy, suitability or completeness are not guaranteed and no warranties of any type, either express or implied, are provided. The information contained herein relates only to this specific product. If this product is combined with other materials, all component properties must be considered. Data may be changed from time to time. Be sure to consult the latest edition.

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