



Actavis
SAFETY DATA SHEET

Prepared to U.S. OSHA, CMA, ANSI, Canadian WHMIS Standards, European Union CLP EC 1272/2008 and the Global Harmonization Standard

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

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

DESCRIPTION: Risedronate Sodium (hemi-pentahydrate with small amounts of monohydrate) Tablets

CHEMICAL NAME: For Active Ingredient: [1-hydroxy-2-(3-pyridinyl)ethylidene]bis[phosphonic acid] monosodium salt

CHEMICAL FAMILY: For Active Ingredient: Pyridinyl Bisphosphonate

FORMULA: For Active Ingredient: C₇H₁₀NO₇P₂Na•2.5 H₂O

RELEVANT USE of the SUBSTANCE: Human Pharmaceutical

USES ADVISED AGAINST: Non-Pharmaceutical Use

HOW SUPPLIED: 35 mg Risedronate Sodium Tablets

OTHER DESIGNATIONS: NDC: NDC:0430-0979-03

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: May 28, 2015

DATE OF REVISION: November 30, 2013

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.

EU 67/548/EEC LABELING AND CLASSIFICATION: According to Article 1 of European Union Council Directive 92/32/EEC, medical products in the finished state for human use (as defined by European Union Council Directives 67/548/EEC and 87/21/EEC) are not subject to the regulations and administrative provisions of European Union Council Directive 92/32/EEC.

EMERGENCY OVERVIEW:

Product Description: This product is supplied as yellow, oval, odorless tablets which have an enteric (delayed release) coating.

Health Hazards: from tablets can cause mechanical irritation to the eyes. Accidental ingestion may be harmful. Ingestion of large amount may cause significant lowering of blood calcium. In therapeutic use, the most common adverse effects reported have included pain, including back and joint pain, common, heartburn. Serious allergic reactions, such as hives, swelling of face, lips, tongue, or throat have been reported, as well as eye inflammation. Therapeutic use may cause additional adverse effects on the gastrointestinal, musculoskeletal, and blood systems. May cause harm to fetus, and fertility, based on animal data. These effects may be possible as a result of workplace exposure. Refer to Section 11 (Toxicological Information) for additional information on adverse effects.

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: The active ingredient of this product can cause long-term harm to aquatic organisms. 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

CHEMICAL NAME	CAS #	EINECS #	% w/v	LABEL ELEMENTS EU Classification (67/548/EEC) GHS & EU Classification (1272/2008 EC) Risk Phrases/Hazard Statements
ACTIVE INGREDIENT				
Risedronate Sodium Monohydrate [1-hydroxy-2-(3-pyridinyl)ethylidene]bis [phosphonic acid] monosodium salt	115436-72-1	Not Listed	Proprietary	SELF CLASSIFICATION <u>EU 67/548</u> Classification: Reproductive Toxicity Cat. 3, Harmful, Irritant Risk Phrase Codes: R62, R63, R22, R36/38 Hazard Symbols: Xn/Xi <u>GHS and EU 1272/2008</u> Classification: Reproductive Toxicity Cat 2, Acute Oral Toxicity Cat. 4, Skin Irritation Cat. 2, Eye Irritation Cat. 2A Hazard Codes: H361fd, H302, H315, H319 Hazard Symbol/Pictogram: GHS07, GHS08
EXCIPIENTS				
Edetate Disodium	6381-92-6	For Anhydrous: 200-449-4	Proprietary	EU 67/548: Classification: Not applicable. GHS & EU 1272/2008: Classification: Not applicable.
Ferric Oxide Yellow	20344-49-4	Not Listed	Proprietary	EU 67/548: Classification: Not applicable. GHS & EU 1272/2008: Classification: Not applicable.
Magnesium Stearate	557-04-0	209-150-3	Proprietary	EU 67/548: Classification: Not applicable. GHS & EU 1272/2008: Classification: Not applicable.
Methacrylic Acid Copolymer Type A	33434-24-1	Not Listed	Proprietary	EU 67/548: Classification: Not applicable. GHS & EU 1272/2008: Classification: Not applicable.
Microcrystalline Cellulose, Silicified	9004-34-6	232-674-9	Proprietary	EU 67/548: Classification: Not applicable. GHS & EU 1272/2008: Classification: Not applicable.
Polysorbate 80	9005-65-6	NLP# 500- 019-9	Proprietary	EU 67/548: Classification: Not applicable. GHS & EU 1272/2008: Classification: Not applicable.
Simethicone	8050-81-5	Not Listed	Proprietary	EU 67/548: Classification: Not applicable. GHS & EU 1272/2008: Classification: Not applicable.
Sodium Starch Glycolate	9063-38-1	Not Listed	Proprietary	EU 67/548: Classification: Not applicable. GHS & EU 1272/2008: Classification: Not applicable.
Stearic Acid	57-11-4	200-313-4	Proprietary	SELF CLASSIFICATION <u>EU 67/548</u> Classification: Not Applicable <u>EU/GHS 1272/2008</u> Classification: Acute Oral Toxicity Cat. 5, Acute Dermal Toxicity Cat. 5 Hazard Statement Codes: H303 + H313 Hazard Symbol/Pictogram: None Applicable
Talc	14807-96-6	238-877-9	Proprietary	EU 67/548: Classification: Not applicable. GHS & EU 1272/2008: Classification: Not applicable.
Triethyl Citrate	77-93-0	201-070-7	Proprietary	SELF-CLASSIFICATION <u>EU 67/548</u> Classification: Harmful, Irritant Risk Phrase Codes: R20, R36/37 Hazard Symbols: Xn/Xi <u>GHS and EU 1272/2008</u> Classification: Acute Inhalation Toxicity Cat. 4, Eye Irritation Cat. 2A, STOT (Inhalation-Respiratory Irritation) SE Cat. 3 Hazard Codes: H332, H319, H335 Hazard Symbol/Pictogram: GHS07, GHS08

See Section 16 for full classification information.

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.

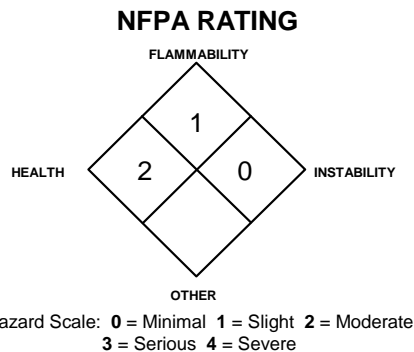
UNSUITABLE EXTINGUISHING MEDIA: None known.

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 Mechanical Impact: Not sensitive.

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-incident releases. Access to the spill areas should be restricted. Sweep up spilled product carefully, avoiding the generation of airborne dusts.

All Spills: 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 product. 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. 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. Use of this product in the workplace 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.

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:

CHEMICAL NAME	CAS #	EXPOSURE LIMITS IN AIR							
		ACGIH-TLVs		OSHA-PELs		NIOSH-RELS		NIOSH	OTHER
		TWA mg/m ³	STEL mg/m ³	TWA mg/m ³	STEL mg/m ³	TWA mg/m ³	STEL mg/m ³	IDLH mg/m ³	
Risedronate Sodium	115436-72-1	NE	NE	NE	NE	NE	NE	NE	Actavis OEL 3 µg/m ³
Edetate Disodium	6381-92-6	NE	NE	NE	NE	NE	NE	NE	NE
Ferric Oxide Yellow Exposure limits given are for iron oxide (CAS# 1309-37-1)	20344-49-4	5 (resp. fract.)	NE	10 (fume)	NE	5 (dust and fume, as Fe)	NE	2500 (dust & fume, as Fe)	DFG MAK: With the exception of iron oxides which are not biologically available Carcinogen: IARC-3, MAK-3B, TLV-A4
Microcrystalline Cellulose, Silicified Exposure limits are for cellulose	9004-34-6	10	NE	15 (total dust), 5 (respirable fraction)	NE	10 (total dust), 5 (resp. fraction)	NE	NE	NE
Methacrylic Acid Copolymer	33434-24-1	NE	NE	NE	NE	NE	NE	NE	NE
Magnesium Stearate Exposure limits are for Stearates	557-04-0	10	NE	NE	NE	NE	NE	NE	Carcinogen: TLV-A4
Polysorbate 80	9005-65-6	NE	NE	NE	NE	NE	NE	NE	NE
Simethicone	8050-81-5	NE	NE	NE	NE	NE	NE	NE	NE
Sodium Starch Glycolate	9063-38-1	NE	NE	NE	NE	NE	NE	NE	NE
Stearic Acid	57-11-4	NE	NE	NE	NE	NE	NE	NE	NE
Talc	14807-96-6	2 (resp. fract.)	NE	20 mppcf (containing < 1% quartz)	NE	2 (respirable dust) and < 1% quartz	NE	NE	Carcinogen: IARC-3, MAK-3B (respirable fraction), TLV-A4
Triethyl Citrate	77-93-0	NE	NE	NE	NE	NE	NE	NE	NE

NE = Not Established

NIC: Notice of Intended Change

See Section 16 for Definitions of Other Terms Used

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.

MAGNESIUM STEARATE:

New Zealand: TWA = 10 mg/m³ (inspirable dust), JAN 2002

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 (respirable), 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, JAN 1999

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), JAN 1993

United Kingdom: TWA = 4 mg/m³ (respirable), 2005

United Kingdom: TWA = 10 mg/m³ (inhalable), 2005

United Kingdom: TWA = 5 mg(Fe)/m³; STEL = 10 mg(Fe)/m³, 2005

In Argentina, Bulgaria, Colombia, Jordan, Singapore, Vietnam check ACGIH TLV

MICROCRYSTALLINE CELLULOSE, SILICIFIED:

Belgium: TWA = 10 mg/m³, MAR 2002

France: VME = 10 mg/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 = W 6 mg/m³, resp, JAN 2011

United Kingdom: TWA = 10 mg/m³; STEL = 20 mg/m³ (inhal. dust), OCT 2007

United Kingdom: TWA = 4 mg/m³ (resp. dust), OCT 2007

In Argentina, Bulgaria, Colombia, Jordan, Singapore, Vietnam, check ACGIH TLV

STEARIC ACID:

Russia: STEL = 5 mg/m³, JUN 2003

TALC:

Australia: TWA = 2.5 mg/m³, JUL 2008

Austria: MAK-TMW = 2 mg/m³, resp, 2007

Belgium: TWA = 2 mg/m³, MAR 2002

Denmark: TWA = 0.3 f/cc, carc, MAY 2011

Finland: TWA = 0.5 mg/m³, NOV 2011

Finland: TWA = 5 mg/m³, granulated, SEP 2009

Iceland: TWA = 0.3 f/cc, NOV 2011

Japan: OEL = 0.5 mg/m³ (resp. dust), 2 mg/m³ (total dust), MAY 2009

Korea: TWA = 2 mg/m³, 2006

Mexico: TWA = 2 mg/m³ (respirable), 2004

The Netherlands: MAC-TGG = 1 mg/m³, 2003

New Zealand: TWA = 2 mg/m³ (respirable dust), JAN 2002

Peru: TWA = 2 mg/m³, JUL 2005

Sweden: TWA = 2 mg/cm³ (total dust); TWA = 1 mg/cm³ (resp. dust), JUN 2005

Switzerland: MAK-W = 2 mg/m³, DEC 2006

United Kingdom: TWA = 1 mg/m³ (resp. dust), OCT 2007

In Argentina, Bulgaria, Colombia, Jordan, Singapore, Vietnam check ACGIH TLV

PERSONAL PROTECTIVE EQUIPMENT: Use of personal protective equipment must be in compliance with U.S. OSHA 29 CFR Subpart I (beginning at 1910.132), Canadian CSA Standards Z94.4-02 and Z94.3-02, EU EN 529:2005, CEN/TR 15419:2006, and CR 13464:1999. Please reference applicable regulations and standards for relevant details.

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.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION (Continued)

PERSONAL PROTECTIVE EQUIPMENT (continued):

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.

COLOR: As described in Section 2.

ODOR: Odorless.

ODOR THRESHOLD: Not applicable.

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.

COLOR: White to off-white.

MOLECULAR FORMULA: C₇H₁₀NO₇P₂Na•2.5 H₂O

MOLECULAR WEIGHT: 350.13

ODOR: Slight.

ODOR THRESHOLD: Not available.

BOILING POINT @ 760 mmHg: 692.3°C (1278) [predict.]

MELTING POINT: 252-262°C (485.6-835°F)

VAPOR PRESSURE (air = 1) @ 25°C: 4.03E-20 mmHg [predict.]

SPECIFIC GRAVITY (water = 1): Not available.

EVAPORATION RATE (nBuAc = 1): Not applicable.

pH: 4.1

FLASH POINT: 372.5°C (705.2) [predict.]

DECOMPOSITION TEMPERATURE: Not available.

SOLUBILITY IN WATER @ 25°C: Soluble in water.

COEFFICIENT WATER/OIL DISTRIBUTION: Log P: 4.5

OTHER SOLUBILITIES: Soluble in chloroform, dimethylsulfoxide, methanol, and ethanol.

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, 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 dusts generated by damaged tablets of this product may irritate the nose, throat, and lungs. In addition, inhalation may result in adverse effects as described under 'Other Potential Health Effects'.

Contact with Skin or Eyes: It is anticipated that this product may irritate contaminated skin or eyes. Symptoms of skin contact may include itching and redness. Symptoms of eye contact can include redness, pain, and watering (mechanical irritation).

Skin Absorption: No information is available on possible skin absorption.

Ingestion: Ingestion of this product (i.e., through poor hygiene practices) may irritate the mouth, throat, and other tissues of the gastrointestinal system. Ingestion may cause other effects described under 'Other Potential Health Effects'.

Injection: Not a potential route of exposure for tablets.



OTHER POTENTIAL HEALTH EFFECTS-Therapeutic Doses: In therapeutic use, the most common adverse effects reported have included pain, including back and joint pain, common, heartburn. Serious allergic reactions, such as hives, swelling of face, lips, tongue, or throat have been reported. Therapeutic use may cause additional adverse effects on the gastrointestinal, musculoskeletal, and blood systems. May cause harm to fetus, and fertility, based on animal data. These effects may be possible as a result of workplace exposure. The actual risk in the workplace is not known. Body systems adversely affected during therapeutic use are provided below.

- **Blood System:** Reduced blood flow to bones causing damage
- **Body as a Whole:** Infection, weakness, flu syndrome, peripheral swelling.
- **Cardiovascular System:** High blood pressure.
- **Central Nervous System:** Headache, dizziness, depression, insomnia.
- **Eyes:** Formation of cataracts, eye inflammation.

HAZARDOUS MATERIAL IDENTIFICATION SYSTEM

HEALTH HAZARD	(BLUE)	2*
FLAMMABILITY HAZARD	(RED)	1
PHYSICAL HAZARD	(YELLOW)	0

PROTECTIVE EQUIPMENT

EYES	RESPIRATORY	HANDS	BODY
	SEE SECTION 8		SEE SECTION 8

For Routine Industrial Use and Handling Applications

Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate
3 = Serious 4 = Severe * = Chronic hazard

11. TOXICOLOGICAL INFORMATION (Continued)

OTHER POTENTIAL HEALTH EFFECTS-Therapeutic Doses (continued):

- **Gastrointestinal System:** Abdominal pain, constipation, nausea, diarrhea, heartburn, esophagitis, esophageal ulcers and esophageal erosions, difficulty or painful swallowing. Rarely, gastric and duodenal ulcers with oral bisphosphonate use, some severe and with complications have been reported.
- **Hypersensitivity Reactions:** Hypersensitivity reactions (angioedema, generalized rash, bullous skin reactions), and eye inflammation (iritis, uveitis) have been reported rarely.
- **Metabolic and Nutritional:** Small, asymptomatic decreases in serum calcium and phosphate may occur.
- **Musculoskeletal System:** Musculoskeletal (bone, muscle, or joint) pain, arthritis. Severe and occasionally incapacitating bone, joint, and/or muscle pain. Rarely, atypical femur fractures most commonly occur with minimal or no trauma to the affected area.
- **Reproductive System:** Potential harm to fetus and fertility, based on animal data,
- **Respiratory System:** Bronchitis, laryngitis, nasal inflammation, runny nose, increased cough.
- **Skin:** Rash.
- **Urogenital System:** Urinary infection.

HEALTH EFFECTS OR RISKS FROM EXPOSURE: An Explanation in Lay Terms. Exposure to this product may cause the following health effects:

Acute: Accidental ingestion may be harmful or cause effects described under 'Other Potential Health Effects'. Eye contact with dusts may cause mechanical irritation.

Chronic: Chronic exposure may lead to symptoms described under 'Other Potential Health Effects'. No chronic effects have been reported from workplace exposure.

TARGET ORGANS: It is anticipated that for Occupational Exposure the target organs are: **Acute:** Skin, eyes, respiratory system. **Chronic:** Potential for fetal harm. In therapeutic use this product may have an impact on the body systems listed under 'Other Potential Health Effects'.

IRRITANCY OF PRODUCT: Dusts from this product may irritate contaminated tissue.

SENSITIZATION TO THE PRODUCT: In therapeutic use, angioedema (swelling of mouth, throat and face), generalized rash, bullous skin reactions), and eye inflammation (iritis, uveitis) have been reported rarely.

TOXICITY DATA: The following toxicity data are currently available for the active ingredient. Additional data are available for excipients, but are not provided in this SDS. Contact Actavis for more information.

RISEDRONATE SODIUM:

TDLo (Oral-Human) 1800 µg/kg/3 days-intermittent: Sense Organs and Special Senses (Eye): iritis
LD₅₀ (Oral-Rat) 1377 mg/kg
TDLo (Oral-Dog) 182 mg/kg/1 year-intermittent: Musculoskeletal: other changes

RISEDRONATE SODIUM (continued):

TDLo (Subcutaneous-Rat) 50 µg/kg: Behavioral: analgesia; Biochemical: Metabolism (Intermediary): effect on inflammation or mediation of inflammation
TDLo (Subcutaneous-Mouse) 100 µg/kg: Behavioral: analgesia

ADDITIONAL ANIMAL TOXICITY DATA: Risedronate demonstrated potent anti-osteoclast, anti-resorptive activity in ovariectomized rats and mini-pigs. Bone mass and biomechanical strength were increased dose-dependently at daily oral doses up to 4 and 25 times the recommended human dose of 5 mg/day for rats and mini-pigs, respectively. Risedronate treatment maintained the positive correlation between BMD and bone strength and did not have a negative effect on bone structure or mineralization. In intact dogs, Risedronate induced positive bone balance at the level of the bone remodeling unit at oral doses ranging from 0.5 to 1.5 times the human dose of 5 mg/day.

In dogs treated with an oral dose approximately 5 times the human dose of 5 mg/day, Risedronate caused a delay in fracture healing of the radius. The observed delay in fracture healing is similar to other bisphosphonates. This effect did not occur at a dose approximately 0.5 times the human daily dose.

The Schenk rat assay, based on histologic examination of the epiphyses of growing rats after drug treatment, demonstrated that Risedronate did not interfere with bone mineralization even at the highest dose tested, which was approximately 3500 times the lowest anti-resorptive dose in this model (1.5 mcg/kg/day) and approximately 800 times the human dose of 5 mg/day. This indicates that this product administered at the therapeutic dose is unlikely to induce osteomalacia.

Dosing multiples provided above are based on the recommended human osteoporosis dose of 5 mg/day and normalized using body surface area (mg/m²).

CARCINOGENIC POTENTIAL OF COMPONENTS: The following information is available for the active ingredient.

In a 104-week carcinogenicity study, rats were administered daily oral doses up to approximately 8 times the human Paget's disease dose of 30 mg/day. There were no significant drug-induced tumor findings in male or female rats. The high dose male group was terminated early in the study (Week 93) due to excessive toxicity, and data from this group were not included in the statistical evaluation of the study results. In an 80-week carcinogenicity study, mice were administered daily oral doses approximately 6.5 times the human dose. There were no significant drug-induced tumor findings in male or female mice. This material is not listed by agencies tracking the carcinogenic potential of chemical compounds.

The excipient components are listed by agencies tracking the carcinogenic potential of chemical compounds, as follows:

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): ACGIH TLV-A4 (Not Classifiable as a Human Carcinogen)

SODIUM STARCH GLYCOLATE: IARC-3 (Unclassifiable as to Carcinogenicity in Humans)

TALC: ACGIH TLV-A4 (Not Classifiable as a Human Carcinogen); IARC-3 (Unclassifiable as to Carcinogenicity in Humans); MAK-3B [respirable fraction]: (Substances Which Cause Concern that They 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.)

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.

11. TOXICOLOGICAL INFORMATION (Continued)

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: 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.

Animal Data: 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 Risedronate 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 peri-parturient 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/m^2). 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 Paget's disease dose of 30 mg/day and normalized using body surface area (mg/m^2). 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 Risedronate is excreted in human milk. 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.

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 may be harmful to marine organisms. The following aquatic toxicity data are available for the active ingredient.

RISEDRONATE SODIUM:

LC₅₀ (fishes) 96 hours = 381 mg/L

EC₅₀ (*Daphnia magna*) 184 mg/L

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

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.

12. ECOLOGICAL INFORMATION (Continued)

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 no 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 is exempted 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.

Chemical Safety Assessment: No Data Available. The chemical safety assessment is required for some substances according to European Union Regulation (EC) 1907/2006, Article 14.

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. COMBUSTIBLE IF EXPOSED TO HIGH TEMPERATURES. Do not take internally without prescription. Avoid contact with skin, eyes, and clothing. Keep container closed. Use gloves, safety glasses, and appropriate respiratory and body protection.

16. OTHER INFORMATION (Continued)

ANSI LABELING (continued): FIRST-AID: If exposed, seek immediate medical attention. If swallowed, do not induce vomiting. If alert, give victim up to three glasses of water. Never give anything by mouth to an unconscious person. In case of contact, immediately flush skin with copious amounts of warm water for 20 minutes. Remove contaminated clothing and shoes. If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. **IN CASE OF FIRE:** Use water fog, dry chemical or CO₂, or alcohol foam. **IN CASE OF SPILL:** Refer to Safety Data Sheet for complete spill response procedures. Spill response should be performed by persons properly trained to do so. Decontaminate area with bleach and detergent solution and triple rinse area. Place spill debris in a suitable container. Refer to SDS 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.

EU LABELING AND CLASSIFICATION 67/548/EEC: According to Article 1 of European Union Council Directive 92/32/EEC, medical products in the finished state for human use (as defined by European Union Council Directives 67/548/EEC and 87/21/EEC) are not subject to the regulations and administrative provisions of European Union Council Directive 92/32/EEC.

CLASSIFICATION FOR COMPONENTS:

Full Text Global Harmonization AND EU CLP Regulation (EC) 1272/2008:

Risedronate Sodium: This is a self-classification.

Classification: Reproductive Toxicity Category 2, Acute Oral Toxicity Category 4, Skin Irritation Category 2, Eye Irritation Category 2A

Hazard Statements: H361fd: Suspected of damaging fertility. Suspected of damaging the unborn child. H302: Harmful if swallowed. H319: Causes serious eye irritation. H315: Causes skin irritation.

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: This is a self-classification.

Classification: Acute Inhalation Toxicity Category 4, Eye Irritation Category 2A, Specific Target Organ Toxicity (Inhalation-Respiratory Irritation) Single Exposure Category 3

Hazard Statements: H332: Harmful if inhaled. H319: Causes serious eye irritation. H335: May cause respiratory irritation.

All Other Components: No classification has been published or is applicable.

Full Text EU 67/548/EEC:

Risedronate Sodium: This is a self-classification.

Classification: Reproductive Toxicity Category 3, Harmful, Irritant

Risk Phrases: R62: Possible risk of impaired fertility. R63: Possible risk of harm to the unborn child. R22: Harmful if swallowed. R36/38: Irritating to eyes and skin.

Triethyl Citrate: This is a self-classification.

Classification: Harmful, Irritant

Risk Phrases: R20: Harmful if inhaled. R36/37: Irritating to eyes and respiratory system.

All Other Components: No classification has been published or 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: May 2015: Review and up-date for current data and format.

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.

PREPARED BY: CHEMICAL SAFETY ASSOCIATES, Inc. • PO Box 1961, Hilo, HI 96721 • 800/441-3365 • 808/969-4846

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