

**Product Name:** Terazosin Monohydrochloride Dihydrate  
**Issued:** Dec-21-2012

## SAFETY DATA SHEET

### Section 1. Identification of the substance/mixture and of the company/undertaking

#### 1.1 Product Identifier

**Product Name:** Terazosin Monohydrochloride Dihydrate  
**Chemical Name:** 1-(4-Amino-6-7-dimethoxy-2-quinazolinyl)4-(2-tetrahydrofuranlycarbonyl)piperazine Hydrochloride Dihydrate  
**Synonyms:** Terazosin Hydrochloride Dihydrate; Terazosin; Terazosin Hydrochloride  
**Drug Code Number:** 81831: 44735: 66398

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

**Recommended use:** Pharmaceuticals

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

**Supplier:** AbbVie Inc.  
North Chicago, IL 60064  
U.S.A.  
1-800-255-5162  
+1-847-937-7433

**Manufacturer European:** AbbVie Ireland Pharmaceutical Operations  
Manorhamilton Road  
Sligo  
IRELAND

**Customer Service Telephone:** 1-800-255-5162 (US and Canada only)  
+1-847-937-7433

**E-mail Address:** AbbVie.SDS@abbvie.com

#### 1.4 Emergency telephone number

**Emergency Telephone:** CHEMTREC: 1(800) 424-9300 (in USA and Canada)  
or +1-703-527-3887 (international)

### Section 2. Hazards identification

#### 2.1 Classification of the substance or mixture

Regulation (EC) No 1272/2008

**Skin corrosion/irritation** Category 2  
**Serious eye damage/eye irritation** Category 2  
**Reproductive toxicity** Category 2  
**Specific target organ systemic toxicity (single exposure)** Category 3  
**None**

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## Section 2. Hazards identification

**Classification according to EU Directives 67/548/EEC or 1999/45/EC**

**Indication of danger:** Xi - Irritant  
**Risk Phrases:** R36 - Irritating to eyes  
R37 - Irritating to respiratory system  
R38 - Irritating to skin  
R62 - Possible risk of impaired fertility

### 2.2 Label elements



**Signal Word:** Warning

**Hazard Statements:** H315 - Causes skin irritation  
H319 - Causes serious eye irritation  
H335 - May cause respiratory irritation  
H361 - Suspected of damaging fertility or the unborn child

P302 + P352 - IF ON SKIN: Wash with plenty of soap and water  
P280 - Wear protective gloves/protective clothing/eye protection/face protection  
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing  
P304 + P340 - IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing  
P312 - Call a POISON CENTER or doctor/physician if you feel unwell  
P403 + P233 - Store in a well-ventilated place. Keep container tightly closed

### 2.3 Other hazards

Not determined

## Section 3. Composition/information on ingredients

Chemical Name	Percent	EINECS/ELINCS Number	EEC Classification	EU - GHS Substance Classification	REACH No.
Terazosin Hydrochloride 70024-40-7	98-100	NA	Xi; R36/37/38, R62	STOT SE 3 (H335) Skin Irrit. 2 (H315) Eye Irrit. 2 (H319) Repro 2 (H361)	No data available

Not Hazardous\* - Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System.

**For the full text of the R-phrases mentioned in this Section, see Section 16**

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For the full text of the H-Statements mentioned in this Section, see Section 16

## **Section 4. First aid measures**

### **4.1 Description of first aid measures**

**Eye Contact:** Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Skin Contact:** Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Inhalation:** Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Ingestion:** Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Protection of First-aiders:** Use personal protective equipment

### **4.2 Most important symptoms and effects, both acute and delayed**

**Signs and Symptoms:** Clinical data suggests the following: headaches, lightheadedness, nausea, dizziness, fatigue, ringing in the ear, fast heart rate, palpitation, nasal congestion, decreased blood pressure. These clinical signs are generally of short duration and mild. Clinical overdose may result in the following: vomiting, abdominal pain, diarrhea.

**Medical Conditions Aggravated by Exposure:** None known from occupational exposure. Data suggest any pre-existing ailments in the following organs: cardiovascular system.

### **4.3 Indication of any immediate medical attention and special treatment needed**

**Notes To Physician:** Treat symptomatically

**Additional Information:** These effects are of short duration.

## **Section 5. Firefighting measures**

### **5.1 Extinguishing Media**

**Suitable Extinguishing Media:** Use extinguishing agent suitable for type of surrounding fire

**Unsuitable Extinguishing Media:** Not determined

### **5.2 Special hazards arising from the substance or mixture**

**Special Exposure Hazards:** This material is capable of forming explosive dust clouds in air, therefore, measures must be taken to avoid ignition. This material is particularly sensitive to ignition by electrostatic discharge.

### **5.3 Advice for firefighters**

**Protective Equipment and Precautions for Firefighters:** As in any fire, wear self-contained breathing apparatus and full protective gear

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## Section 6. Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

**Personal Precautions:** For personal protection see section 8

### 6.2. Environmental precautions

**Environmental Precautions:** Contain material and prevent release to waterways or soil.

### 6.3. Methods and material for containment and cleaning up

**Methods for Cleaning Up:** Recover product and place in an appropriate container for disposal.

**Incompatibilities:** Oxidizers.

### 6.4. Reference to other sections

Refer to Sections 8, 12, and 13 for further information.

## Section 7. Handling and storage

### 7.1. Precautions for safe handling

Handle in accordance with good industrial hygiene and safety practice.

### 7.2. Conditions for safe storage, including any incompatibilities

Store according to label instructions

### 7.3. Specific end use(s)

**Recommended use:** Pharmaceuticals

## Section 8. Exposure controls/personal protection

### 8.1. Control parameters

#### Exposure limits:

Chemical Name	Employee Exposure Limit	Skin Notation
Terazosin Hydrochloride 70024-40-7	10 mcg/m <sup>3</sup> in 8-hour TWA	None

### 8.2. Exposure controls

**Engineering Controls:** Use inside a hood, glovebox or process enclosure.

**Respiratory Protection:** An approved respirator (i.e. NIOSH, EN, etc.) should be worn when exposures are expected to exceed the applicable limits.

**Eyes:** Wear eye protection appropriate to handling activities.

**Gloves:** Impervious gloves.

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**Other PPE Data:** Wear appropriate body coverings if contact may occur.

**Environmental Exposure Controls:** Not determined

## Section 9. Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

<b>Appearance:</b>	White to light yellow Crystalline Powder
<b>Odor:</b>	Odorless.
<b>Odor Threshold:</b>	Not determined
<b>pH:</b>	4.0 as a 1% solution.
<b>Boiling Pt. @ 760 mm Hg (°C):</b>	Not determined.
<b>Melting/Freezing Point (°C):</b>	271-274
<b>Flash Point (°C):</b>	Not determined.
<b>Evaporation Rate at 20°C:</b>	Not determined.
<b>Flammability (Solid):</b>	Not determined.
<b>Lower Explosive Limit:</b>	Not determined.
<b>Upper Explosive Limit:</b>	Not determined.
<b>Vapor Pressure (mm Hg):</b>	Not determined.
<b>Vapor Density (Air = 1):</b>	Not determined.
<b>Specific Gravity:</b>	Not determined.
<b>Solubility(ies):</b>	Soluble in: water, methanol.
<b>Partition coefficient: n-octanol/water</b>	Not determined.
<b>Autoignition Temp. (°C):</b>	500-520
<b>Decomposition temperature (°C):</b>	Not determined.
<b>Viscosity (centipoise):</b>	Not determined.
<b>Explosion Severity:</b>	Not determined.
<b>Oxidizer Properties:</b>	Not determined.

### 9.2. Other information

<b>Maximum Pressure Rise (bar):</b>	8.6
<b>Max. rate of pressure rise (bar/sec):</b>	645
<b>Kst Value (bar.m/s):</b>	175
<b>Min. Ignition Energy-Cloud (mJ):</b>	50-100
<b>Min. Explosive Conc. (g/m<sup>3</sup>):</b>	< 100

## Section 10. Stability and reactivity

### 10.1. Reactivity

Not determined

### 10.2. Chemical stability

Stable under normal conditions

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### 10.3. Possibility of hazardous reactions

**Hazardous reactions:** Not determined.

**Self-Heating Tendency:** No exotherms seen below 200 deg C in DSC testing.

### 10.4. Conditions to avoid

Not determined.

### 10.5 Incompatible materials

Oxidizing agents

### 10.6 Hazardous decomposition products

Carbon oxides, Nitrogen oxides (NO<sub>x</sub>), Hydrogen chloride

## **Section 11. Toxicological information**

### 11.1. Information on toxicological effects

#### **Routes of Exposure:**

**Oral:** Yes

**Dermal:** Yes

**Inhalation:** Yes

**Acute Toxicity - Oral:** Data for component (s) given below.

Chemical Name	Acute Test	Value	Units	Species
Terazosin Hydrochloride 70024-40-7	LD50 =	2700-10,000	mg/kg	Mice Rats

**Acute Toxicity - Dermal:** Data for component (s) given below.

Chemical Name	Acute Test	Value	Units	Species
Terazosin Hydrochloride 70024-40-7	LD50 >	2000	mg/kg	Rabbits

**Acute Toxicity - Inhalation:** Not determined.

**Corrosivity:** Not determined.

**Dermal Irritation:** May be a skin irritant.

**Eye Irritation:** Produced mild to moderate eye irritation in rabbits. Recovery after 48 hours.

**Sensitization:** Negative in the maximization assay in guinea pigs at challenge concentrations.

**Toxicokinetics/Metabolism:** Not determined.

**Target Organ Effects:** May cause respiratory tract irritation

**Reproductive Effects:** In animals adverse reproductive effects include: testicular atrophy.  
Data for component (s) given below.

Chemical Name	Species	Dosage	Units	Route	Duration
Terazosin Hydrochloride 70024-40-7	Rats	40	mg/kg	Not specified	Not specified

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**Carcinogenicity:** Not determined.

**Mutagenicity:** Data for component (s) given below.

Chemical Name	Micronucleus Assay	Ames Test:	Mouse Lymphoma Assay	Chromosomal Abbr. Assay
Terazosin Hydrochloride 70024-40-7	Negative	Negative	No Data.	Negative

**Aspiration hazard:** Not determined

**Notes:**

1. ALD: Approximate lethal dosage
2. LC50: Concentration in air that produces 50% mortality
3. LD50: Oral or dermal dosage that produces 50% mortality

## Section 12. Ecological information

### 12.1. Toxicity

Not determined.

### 12.2. Persistence and degradability

Not determined.

### 12.3. Bioaccumulative potential

Not determined

### 12.4. Mobility in soil

Not determined.

### 12.5. Results of PBT or vPvB assessment

Chemical safety report is not required for this substance/product.

### 12.6. Other adverse effects

Do not allow undiluted material or large quantities to reach groundwater, bodies of water or sewer system.

**Notes:**

1. EC50: Concentration in water that produces 50% mortality in *Daphnia* sp.
2. LC50: Concentration in water that produces 50% mortality in fish.
3. EbC50/ErC50: Concentration in water that produces 50% inhibition of growth and in algae.

## Section 13. Disposal considerations

### 13.1 Waste treatment methods

**Waste Disposal Methods:** Disposal should be made in accordance with country, federal, state and local regulations.

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## Section 14. Transport information

### ADR, DOT, ICAO/IATA, IMDG/IMO

**Status:** Not regulated

**14.1. UN Number:** Not applicable

**14.2. Proper shipping name:** Not applicable

**14.3. Hazard class:** Not applicable

**14.4. Packing group:** Not applicable

**14.5. Environmental hazard:** Not applicable

**14.6. Special Provisions:** Not applicable

**14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code:** Not applicable

## Section 15. Regulatory Information

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

#### International Inventories

Chemical Name	EINECS/ ELINCS	TSCA	DSL	NDSL	PICCS
Terazosin Hydrochloride 70024-40-7	-	-	-	Not listed.	-

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Terazosin Hydrochloride 70024-40-7	-	-	-	-	-	

#### Legend

**EINECS/ELINCS** - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List

**PICCS** - Philippines Inventory of Chemicals and Chemical Substances

**ENCS** - Japan Existing and New Chemical Substances

**ISHL** - Japan Industrial Safety and Health Law

**IECSC** - China Inventory of Existing Chemical Substances

**AICS** - Australian Inventory of Chemical Substances

**KECL** - Korean Existing and Evaluated Chemical Substances

#### Carcinogenicity Rating:

Chemical Name	Percent	NTP:	IARC:	ACGIH:
Terazosin Hydrochloride	98-100	Not Listed	Not Listed	Not Listed

#### SARA 313 Information

Chemical Name	Percent	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Terazosin Hydrochloride	98-100	No	Not Applicable	Not applicable

**Immediate Health:** Yes

**Delayed Health:** No

**Fire:** No



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**Sudden Pressure:** No  
**Reactivity:** No  
**RCRA Status:** Not determined.  
**Proposition 65 Status:** Does not contain chemicals known to the state of California to cause cancer or reproductive harm.  
**WHMIS Hazard Class:** Not determined.  
**NFPA Rating:**  
Health: 1  
Fire: 1  
Reactivity: 0

**Notes:**

1. SARA = Superfund Amendments and the Reauthorization Act.
2. CERCLA = Comprehensive Environmental Response, Compensation and Liability Act.
3. FIFRA = Federal Insecticide, Fungicide and Rodenticide Act.
4. TSCA = Toxic Substances Control Act.
5. EC = European Community.
6. WHMIS = Canadian Workplace Hazardous Materials Information System.
7. UN GHS = United Nations Globally Harmonized System for Hazard Identification.

**15.2. Chemical safety assessment**

Chemical safety assessment has not been conducted on the substance/product.

**Section 16. Other information**

**Risk Phrases:** R36 - Irritating to eyes, R37 - Irritating to respiratory system, R38 - Irritating to skin, R62 - Possible risk of impaired fertility

**Full text of H-Statements referred to under sections 2 and 3**

H335 - May cause respiratory irritation, H315 - Causes skin irritation, H319 - Causes serious eye irritation

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