



# SAFETY DATA SHEET



Issuing Date 02-Sep-2017

Revision Date 02-Sep-2017

Revision Number 1

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

### 1.1. Product identifier

**Product Name** Clonidine Hydrochloride Tablets  
**Active Ingredient** Clonidine Hydrochloride

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

**Identified Use** Pharmaceutical  
**Uses advised against** Other than Relevant Use

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

**Manufacturer, Supplier** ACTAVIS, Inc.  
400 Interpace Parkway, Morris Corporate Center III  
Parsippany, NJ 07054  
800-272-5525 [08:00 AM --> 05:00 PM]  
**TEVA**  
1090 Horsham Road  
North Wales, PA 19454  
215-591-3000 [08:00 AM --> 05:00 PM]

For further information, please contact

**E-mail Address** TevaSDSRequest@tevapharm.com

### 1.4. Emergency Telephone Number

**Emergency Telephone Number** United States/Canada/Puerto Rico: 1-800/424-9300 (Chemtrec) [24-hrs]  
International: 01-703-527-3887 (Chemtrec) [24-hours]

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

Exempt from requirements - regulated as a medicinal product.

### 2.2. Label Elements

Exempt from requirements - regulated as a medicinal product

### 2.3. Other hazards

None known

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

N.A.

### 3.2. Mixtures

Chemical Name	EC No	REACH Reg. No	CAS-No	Weight %
Clonidine Hydrochloride	-	Not available	4205-91-8	Proprietary
Excipients	-	Not available	-	Remainder

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

<b>Eye Contact</b>	Flush eyes with water for at least 15 minutes. Get medical attention if eye irritation develops or persists.
<b>Skin Contact</b>	Wash off immediately with plenty of water. Get medical advice/attention if you feel unwell.
<b>Ingestion</b>	If swallowed, rinse mouth with water (only if the person is conscious). Do NOT induce vomiting. Get medical advice/attention if you feel unwell.
<b>Inhalation</b>	Remove person to fresh air. If signs/symptoms continue, get medical attention.

### 4.2. Most important symptoms and effects, both acute and delayed See product insert.

### 4.3. Indication of immediate medical attention and special treatment needed

**Notes to Physician** Treat symptomatically.

## SECTION 5: Fire-fighting measures

### 5.1. Extinguishing media

#### **Suitable Extinguishing Media**

Water spray. Carbon dioxide (CO<sub>2</sub>). Foam. Dry powder. Halons.

#### **Unsuitable extinguishing media**

No information available.

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

Thermal decomposition can lead to release of irritating gases and vapors.

### 5.3. Advice for firefighters

#### **Special protective equipment for firefighters**

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

## SECTION 6: Accidental release measures

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

Avoid all unnecessary contact.

#### **6.1.1. For non-emergency personnel**

**Protective equipment** See section 8

**Emergency procedures** Evacuate the danger area and alert emergency team

#### **6.1.2. For emergency responders**

See section 8

### 6.2. Environmental Precautions

Prevent entry into waterways, sewers, basements or confined areas. Prevent further leakage or spillage if safe to do so.

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

#### **6.3.1. Methods for Containment**

No information available.

#### **6.3.2. For cleaning up**

Take up mechanically and collect in suitable container for disposal.

#### **6.3.3. Other information**

No information available

### 6.4. Reference to other sections

See Sections 8 & 13 for additional information.

## SECTION 7: Handling and storage

### 7.1. Precautions for Safe Handling

#### **Handling**

Avoid contact with skin, eyes and clothing. Handle in accordance with good industrial hygiene and safety practice. Do not breathe vapors/dust. Provide appropriate exhaust ventilation at places where dust is formed.

#### **Hygiene Measures**

Handle in accordance with good industrial hygiene and safety practice.

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

Store in accordance with: label.

### 7.3. Specific end use(s)

#### **Exposure Scenario**

No information available.

#### **Other Guidelines**

No information available.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### **Exposure Limits**

No exposure limits determined for this mixture.

#### **Biological occupational exposure limits**

No information available.

#### **Derived No Effect Level (DNEL)**

No information available.

#### **Predicted No Effect Concentration (PNEC)**

No information available.

### 8.2. Exposure controls

#### **Engineering Measures**

Provide engineering control.

#### **Personal protective equipment**

##### **Eye/face protection**

Use eye protection appropriate for the task.

##### **Skin protection:**

- Body protection

Use protective clothing appropriate for the task.

- Hand protection

Use appropriate protective gloves.

##### **Respiratory Protection**

Use appropriate respiratory protection.

#### **Environmental exposure controls**

No information available.

## SECTION 9: Physical and chemical properties

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

#### **Appearance**

No information available

#### **Physical State**

Tablets

#### **Flash Point**

No information available

### 9.2. Other information

No information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

No information available.

### 10.2. Chemical Stability

Stable under normal conditions.

### 10.3. Possibility of hazardous reactions

None known.

### 10.4. Conditions to avoid

Heat, flames and sparks.

### 10.5. Incompatible materials.

None in particular.

### 10.6. Hazardous decomposition products

None under normal use.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

#### **acute toxicity**

No hazard expected under normal handling conditions.

#### **skin corrosion/irritation**

No hazard expected under normal handling conditions.

#### **serious eye damage/irritation**

No hazard expected under normal handling conditions.

#### **respiratory or skin sensitization**

No hazard expected under normal handling conditions.

#### **germ cell mutagenicity**

No hazard expected under normal handling conditions.

#### **carcinogenicity**

No hazard expected under normal handling conditions.

#### **reproductive toxicity**

No hazard expected under normal handling conditions.

#### **STOT - single exposure**

No hazard expected under normal handling conditions.

#### **STOT - repeated exposures**

No hazard expected under normal handling conditions.

#### **aspiration hazard**

No hazard expected under normal handling conditions.

### Other Information

No hazard expected under normal handling conditions. .

## SECTION 12: Ecological information

### 12.1. Toxicity

#### **Ecotoxicity effects**

No information available.

### 12.2. Persistence and degradability

No information available.

### 12.3. Bioaccumulative potential

No information available.

### 12.4. Mobility in soil

No information available.

### 12.5. Results of PBT and vPvB assessment

No information available.

### 12.6. Other adverse effects

None known

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

**Waste from Residues/Unused Products** Dispose of in accordance with local regulations.

**Contaminated Packaging** Empty containers should be taken for local recycling, recovery or waste disposal.

### SECTION 14: Transport information

14.1.  
**UN-No** -

14.2.  
**Proper Shipping Name** -

14.3. Transport hazard class(es)  
**ADR / RID / ADN (land transport)** -  
**IMDG (sea transport)** -  
**IATA / ICAO (air transport)** -

14.4.  
**Packing Group** -

14.5. Environmental hazards  
**Marine Pollutant** -

14.6. Special precautions for user  
**Emergency No.** -  
**ADR/RID-Labels** -

14.7.  
**Technical name** -  
**Ship type** -  
**Annex II** -

### SECTION 15: Regulatory information

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

This safety data sheet complies with the requirements of: GHS

#### 15.2. Chemical Safety Assessment

No information available

**SECTION 16: Other information**

**CLP/GHS - Regulation**

**Hazard Statements**

Training appropriate for workers is required to ensure protection of human health and environment.

**Source of data**

R.T.E.C.S. - REGISTRY OF TOXIC EFFECTS OF CHEMICAL SUBSTANCES  
A.C.G.I.H. - AMERICAN CONFERENCE OF INDUSTRIAL HYGIENISTS  
H.S.D.B. - HAZARDOUS SUBSTANCES DATA BANK  
N.I.O.S.H. - NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH  
N.T.P. - NATIONAL TOXICOLOGY PROGRAM  
I.A.R.C. - INTERNATIONAL AGENCY FOR RESEARCH ON CANCER  
ECHA (European chemicals agency) databases  
FDA (Food & Drug administration) database  
EMA (European Medicines agency) documents  
ChemAdvisor  
Chemspider database

**Issuing Date** 02-Sep-2017

**Revision Date** 02-Sep-2017

**Revision Note**

Not applicable

**Disclaimer**

The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, and disposal of the designated material and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

End of Safety Data Sheet