



Material Safety Data Sheet

Material Name: Duraclon®

*** Section 1 - Chemical Product and Company Identification ***

Manufacturer Information

Bioniche Pharma
272 E Deerpath Road
Suite 304
Lake Forest, IL 60045

Phone: 888-258-4199

Emergency # 888-875-1671

*** Section 2 - Hazards Identification ***

Emergency Overview

FINISHED PHARMACEUTICAL PRODUCT
REFER TO PHYSICIANS' DESK REFERENCE
ACTIVE INGREDIENT: HARMFUL
MAY IRRITATE EYES.
AFFECTS CENTRAL NERVOUS SYSTEM/CARDIOVASCULAR SYSTEM

SHORT-TERM INGESTION OR INJECTION CAN CAUSE NAUSEA, BLOOD PRESSURE EFFECTS, DROWSINESS, CONFUSION, AND RESPRATORY DEPRESSION.
MAY CAUSE SENSITIZATION AND ALLERGIC REACTION BY INGESTION OR INJECTION.

Potential Health Effects: Eyes

Direct contact with this solution may cause mild eye irritation.

Potential Health Effects: Skin

Direct contact with this solution may cause mild skin irritation.

Potential Health Effects: Ingestion

No hazard is expected from normal clinical use. See "Therapeutic Side Effects" for information on side effects by ingestion of therapeutic doses.

Potential Health Effects: Inhalation

No hazard is expected from normal clinical use. Inhalation of mists or sprays of this solution may irritate the respiratory system. Inhalation of large amounts may cause respiratory difficulties.

Medical Conditions Aggravated by Exposure

Hypersensitivity to Clonidine, bleeding diathesis, heart disease, and depression.

THERAPEUTIC SIDE EFFECTS: Adverse effects may include low blood pressure, decreased heart rate, rebound high blood pressure, dry mouth, nausea, dizziness, sleepiness, insomnia, fever, anxiety, confusion, constipation, difficulty breathing, weakness, increase in sensitivity to sensory stimuli, pain, and vomiting. Possible allergic reaction if ingested.

Symptoms of overdose include high blood pressure followed by low blood pressure, irregular heartbeat, respiratory depression, apnea, abnormally low body temperature, drowsiness, mental depression and coma, decreased or absent reflexes, irritability, constriction of the pupil, and swelling in lower extremities and feet..

HMIS Ratings: Health: 2 Fire: 0 HMIS Reactivity 0

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

*** Section 3 - Composition / Information on Ingredients ***

CAS #	Component	Percent
4205-91-8	Clonidine hydrochloride	0.01-0.05

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*** Section 4 - First Aid Measures ***

First Aid: Eyes

Flush with running water for 15 minutes holding eyelids open. Seek medical attention if adverse effect occurs.

First Aid: Skin

Wash contaminated area with soap and water. Seek medical attention if irritation or adverse effect occurs.

First Aid: Ingestion

Flush mouth out with water and get medical attention immediately.

First Aid: Inhalation

No specific treatment is necessary since this product is not likely to be hazardous by inhalation. Move person to fresh air immediately and seek medical attention if irritation or adverse effect occurs.

First Aid: Notes to Physician

There is no specific antidote for Clonidine overdose. Supportive care may include atropine sulfate for bradycardia, intravenous fluids and/or vasopressor agents for hypotension. Hypertension associated with overdose has been treated with intravenous furosemide, diazoxide, or alpha-blocking agents such as phentolamine. Naloxone may be a useful adjunct in the treatment of Clonidine induced respiratory depression, hypotension, and/or coma; blood pressure should be monitored since the administration of naloxone has occasionally resulted in paradoxical hypertension. Tolazoline administration has yielded inconsistent results and is not recommended as first-line therapy. Dialysis is not likely to significantly enhance the elimination of Clonidine. Such treatment needs to be provided in a medically-staffed and equipped environment.

*** Section 5 - Fire Fighting Measures ***

General Fire Hazards

See Section 9 for Flammability Properties.

When involved in a fire, this product may decompose and produce irritating fumes and toxic gases.

Hazardous Combustion Products

Thermal decomposition may result in the emission of carbon monoxide, carbon dioxide, nitrogen oxides and hydrogen chloride.

Extinguishing Media

Use media suitable for fire in surrounding area.

Fire Fighting Equipment/Instructions

Wear full protective clothing and positive pressure self-contained breathing apparatus.

NFPA Ratings: Health: 2 Fire: 0 Reactivity: 0

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

*** Section 6 - Accidental Release Measures ***

Containment Procedures

Contain the discharged material.

Clean-Up Procedures

Using appropriate protective equipment, wipe up and containerize spilled material. Avoid generation of splashes or sprays during cleanup. Avoid contamination of sewers and waterways. Dispose of spilled material according to local regulations.

Evacuation Procedures

Isolate area. Keep unnecessary personnel away.

Special Procedures

None

*** Section 7 - Handling and Storage ***

Handling Procedures

Storage Temperature (Min./Max.): Controlled Room Temperature: 59 to 86°F (15 to 30°C).

Shelf Life: Two Years

Protect from temperatures below 59°F (15°C) and above 86°F (30°C).

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Storage Procedures

Store at recommended temperatures, in original container tightly closed, away from food. Wear appropriate light-weight gloves during use.

*** Section 8 - Exposure Controls / Personal Protection ***

A: Component Exposure Limits

ACGIH, OSHA, and NIOSH have not developed exposure limits for any of this product's components.

Engineering Controls

None

PERSONAL PROTECTIVE EQUIPMENT

Personal Protective Equipment: Eyes/Face

Not required under normal conditions of therapeutic administration and use.

Personal Protective Equipment: Skin

Not required under normal conditions of therapeutic administration and use.

Personal Protective Equipment: Respiratory

Not required under normal conditions of therapeutic administration and use.

Personal Protective Equipment: General

None

*** Section 9 - Physical & Chemical Properties ***

Appearance:	Clear, Colorless	Odor:	None
Physical State:	Liquid	pH:	5-7
Vapor Pressure:	Not Available	Vapor Density:	Not Available
Boiling Point:	Similar to water	Melting Point:	Not Available
Solubility (H2O):	Complete	Specific Gravity:	Not Available
Evaporation Rate:	Not Available	VOC:	Not Available
Octanol/H2O Coeff.:	Not Available	Flash Point:	Not Applicable
Flash Point Method:	Not Applicable	Upper Flammability Limit (UFL):	Not Applicable
Lower Flammability Limit (LFL):	Not Applicable	Burning Rate:	Not Applicable
Auto Ignition:	Not Applicable		

*** Section 10 - Chemical Stability & Reactivity Information ***

Chemical Stability

This is a stable material.

Chemical Stability: Conditions to Avoid

Avoid temperatures exceeding 86°F (30°C).

Incompatibility

May react with strong oxidizing agents (e.g., peroxides, permanganates, nitric acid, etc.), strong acids, some metals, substances that are incompatible with water.

Hazardous Decomposition

Thermal decomposition may result in the emission of carbon oxides, nitrogen oxides, and hydrogen chloride.

Possibility of Hazardous Reactions

Will not occur.

*** Section 11 - Toxicological Information ***

Acute Dose Effects

A: General Product Information

General Toxicity: Hypertension may develop early and may be followed by hypotension, bradycardia, respiratory depression, hypothermia, drowsiness, decreased or absent reflexes, irritability, and miosis. With large oral overdoses, reversible cardiac conduction defects or arrhythmias, apnea, coma, and seizures have been reported. As little as 100 pg of oral Clonidine has produced signs of toxicity in pediatric patients. Women have a lower mean plasma clearance rate, longer mean plasma half-life, and higher mean peak concentration of clonidine in both plasma and cerebro-spinal fluid (CSF) than do men.

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For Active Ingredient Human Data: TDLo (Oral-Human) 440 µg/kg: Cardiac: pulse rate; Vascular: BP elevation not characterized in autonomic section; Lungs, Thorax, or Respiration: other changes
TDLo (Oral-Woman) 180 pg/kg: Behavioral: coma; Cardiac: pulse rate; Lungs, Thorax, or Respiration: respiratory depression
TDLo (Oral-Human) 1.25 pg/kg: Behavioral: analgesia; Vascular: BP lowering not characterized in autonomic section
TDLo (Oral-Human) 0.004 mg/kg: Cardiac: change in rate, cardiac output; Vascular: BP lowering not characterized in autonomic section
TDLo (Oral-Human) 0.0022 mg/kg: Cardiac: change in rate; Vascular: BP lowering not characterized in autonomic section
TDLo (Oral-Woman) 126 pg/kg/4 weeks-intermittent: Gastrointestinal: other changes
TDLo (Oral-Man) 69 pg/kg: Behavioral: hallucinations, distorted perceptions; Vascular: BP lowering not characterized in autonomic section, pulse pressure increase
TDLo (Oral-Infant) 390 pg/kg: Behavioral: coma; Cardiac: pulse rate; Vascular: BP elevation not characterized in autonomic section
TDLo (Oral-Child) 70 µg/kg: Behavioral: somnolence (general depressed activity); Vascular: BP lowering not characterized in autonomic section; Lungs, Thorax, or Respiration: other changes
TDLo (Oral-Child) 100 pg/kg: Behavioral: irritability; Cardiac: EKG changes not diagnostic of specified effects; Vascular: BP lowering not characterized in autonomic section
TDLo (Intracerebral-Man) 1.43 pg/kg: Behavioral: analgesia; Vascular: BP lowering not characterized in autonomic section
TDLo (Intracerebral-Man) 2.86 pg/kg: Cardiac: change in rate
TDLo (Intravenous-Woman) 0.03 mg/kg: Reproductive: Maternal Effects: uterus, cervix, vagina
TDLo (Unreported-Human) 0.0025 pg/kg: Behavioral: analgesia; Cardiac: change in rate; Vascular: BP lowering not characterized in autonomic section TDLo (Unreported-Man) 2.1 pg/kg: Behavioral: analgesia; Cardiac: change in rate; Vascular: BP lowering not characterized in autonomic section
TDLo (Unreported-Woman) 3 pg/kg: Behavioral: analgesia; Cardiac: change in rate; Vascular: BP lowering not characterized in autonomic section

B: Component Analysis - LD50/LC50

Clonidine hydrochloride (4205-91-8)

Oral LD50 Rat 126 mg/kg; Inhalation LC50 Rat 19.7 mg/m³ 4 h

Carcinogenicity

A: General Product Information

In a 132-week study in rats, Clonidine Hydrochloride administered as a dietary admixture at 5-8 times (based on body surface area) the 50 g/kg MRDHD for hypertension did not show any carcinogenic potential.

B: Component Carcinogenicity

None of this product's components are listed by ACGIH, IARC, OSHA, NIOSH, or NTP.

Mutagenicity

Clonidine was inactive in the Ames test of mutagenicity.

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Teratogenicity

PREGNANCY CATEGORY C-RISK CANNOT BE RULED OUT, Clonidine readily crosses the placenta and its concentrations are equal in maternal and umbilical cord plasma; amniotic fluid concentrations can be 4-times those found in serum. There are no adequate and well-controlled studies in pregnant women during early gestation when organ formation takes place. Studies using epidural Clonidine during labor have demonstrated no apparent adverse effects on the infant at the time of delivery. However, these studies did not monitor the infants for hemodynamic effects in the days following delivery. Clonidine hydrochloride injection should be used during pregnancy only if the potential benefits justify the potential risk to the fetus. Fertility of male or female rats was unaffected by oral Clonidine Hydrochloride doses as high as 150 pg/kg or about 0.5 times the maximum recommended daily human dose (MRDHD). In another experiment, fertility of female rats appeared to be affected at oral dose levels of 500-2000 pg/kg or 2-7 times the MRDHD. Reproduction studies in rabbits at Clonidine Hydrochloride doses up to approximately the MRDHD revealed no evidence of teratogenic or embryotoxic potential. In rats, however, doses as low as one-third the MRDHD were associated with increased resorptions in a study in which dams were treated continuously from 2 months prior to mating. Increased resorptions were not associated with treatment with the same or higher doses up to 0.5 times the MRDHD when dams were treated on days 6-15 of gestation. Increased resorption was observed at higher levels (7-times the MRDHD) in rats and mice treated on days 1-14 of gestation.

*** Section 12 - Ecological Information ***

Ecotoxicity

A: General Product Information

No information available for the product.

B: Component Analysis - Ecotoxicity - Aquatic Toxicity

No ecotoxicity data are available for this product's components.

*** Section 13 - Disposal Considerations ***

US EPA Waste Number & Descriptions

Component Waste Numbers

No EPA Waste Numbers are applicable for this product's components.

Disposal Instructions

Disposal must be in accordance with applicable federal, state, and local laws and regulations. Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

See Section 7 for Handling Procedures. See Section 8 for Personal Protective Equipment recommendations.

*** Section 14 - Transportation Information ***

US DOT Information

Shipping Name: Not Regulated

*** Section 15 - Regulatory Information ***

US Federal Regulations

Component Analysis

None of this products components are listed under SARA Section 302 (40 CFR 355 Appendix A), SARA Section 313 (40 CFR 372.65), or CERCLA (40 CFR 302.4).

State Regulations

Component Analysis - State

None of this product's components are listed on the state lists from CA, MA, MN, NJ, PA, or RI.

Component Analysis - WHMIS IDL

No components are listed in the WHMIS IDL.

Additional Regulatory Information

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Component Analysis - Inventory

Component	CAS #	TSCA	CAN	EEC
Clonidine hydrochloride	4205-91-8	No	DSL	EINECS

* * * Section 16 - Other Information * * *

Other Information

The information herein is presented in good faith and believed to be accurate as of the effective date given. However, no warranty, expressed or implied, is given. It is the buyer's responsibility to ensure that its activities comply with Federal, State or provincial, and local laws.

Key/Legend

EPA = Environmental Protection Agency; TSCA = Toxic Substance Control Act; ACGIH = American Conference of Governmental Industrial Hygienists; IARC = International Agency for Research on Cancer; NIOSH = National Institute for Occupational Safety and Health; NTP = National Toxicology Program; OSHA = Occupational Safety and Health Administration., NJTSR = New Jersey Trade Secret Registry.

End of Sheet