

Catapres®

Version 1.0 Revision Date: 06/03/2015 MSDS Number: 000000015185 Date of last issue: -
Date of first issue: 06/03/2015

SECTION 1. IDENTIFICATION

Product name : Catapres®, Catapres® tablets, Catapresan® tablets, Catapresan® plaster, Catapresan® capsules, Dixarit® tablets, Catapres® capsules

Synonyms : Active ingredient: Clonidine hydrochloride <= 1%
Catapresan® tablets 0.075 mg, 0.1 mg, 0.15 mg, 0.2 mg and 0.3 mg tablets, Catapres® tablets 0,1 mg, 0,2mg and 0,3 mg, Catapresan® 2.5 mg/plaster, 5.0 mg/plaster, 7.5 mg/plaster

Product code : 000000015185

Manufacturer or supplier's details

Company name of supplier : Boehringer-Ingelheim Pharmaceuticals, Incorporated

Address : 900 Ridgebury Road
Ridgefield, Connecticut
06877-0368

Emergency telephone number : +1-800-424-9300 CHEMTREC Emergency Phone Number
CHEMTREC – 24 Hours

Routine Contact Number : (203) 778-7759

Recommended use of the chemical and restrictions on use

Recommended use : Mixture for production of finished medicinal products.

Prepared by : Corp. Div. EHS & Sustainability / Global EHS Services
EHS-service@boehringer-ingelheim.com

SECTION 2. HAZARDS IDENTIFICATION**GHS Classification (Hazard Communication Standard (HCS) 29 CFR 1910.1200)**

Not a hazardous substance or mixture.

GHS Label element (Hazard Communication Standard (HCS) 29 CFR 1910.1200)

Not a hazardous substance or mixture.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Catapres®

Version 1.0 Revision Date: 06/03/2015 MSDS Number: 000000015185 Date of last issue: -
Date of first issue: 06/03/2015

Substance / Mixture : Mixture

Hazardous components

Chemical Name	CAS-No.	Concentration (%)
Clonidine hydrochloride	4205-91-8	< 1

SECTION 4. FIRST AID MEASURES

- General advice : Remove from exposure, lie down.
Take off immediately all contaminated clothing.
Victim to lie down in the recovery position, cover and keep him warm.
First Aid responders should pay attention to self-protection and use the recommended protective clothing
- If inhaled : Keep patient calm, remove to fresh air, seek medical attention.
- In case of skin contact : Wash off thoroughly with ample water.
Seek medical attention.
- In case of eye contact : Immediately wash affected eyes for at least 15 minutes under running water with eyelids held open, consult an eye specialist.
- If swallowed : Rinse mouth.
Drink plenty of water.
Call a physician immediately.
- Most important symptoms and effects, both acute and delayed : Causes damage to organs in contact with skin.

SECTION 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Water
Dry chemical
Foam
Carbon dioxide (CO₂)
- Specific hazards during fire-fighting : In case of fire and/or explosion do not breathe fumes.
Can be released in case of fire:
Carbon oxides
Hydrogen chloride gas
Nitrogen oxides (NO_x)
- Further information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
Fire residues and contaminated fire extinguishing water must

Catapres®

Version	Revision Date:	MSDS Number:	Date of last issue: -
1.0	06/03/2015	000000015185	Date of first issue: 06/03/2015

be disposed of in accordance with local regulations.
Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

Special protective equipment for firefighters : Self-contained breathing apparatus (EN 133)
complete suit protecting against chemicals

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Wear personal protective equipment.
Refer to protective measures listed in sections 7 and 8.
Keep people away from and upwind of spill/leak.
Ensure adequate ventilation.
Knock down dust with water spray jet.
Suppress vapours with waterspray.

Environmental precautions : Do not flush into surface water or sanitary sewer system.

Methods and materials for containment and cleaning up : Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
Clean-up methods - large spillage
Dampen, pick up mechanically and dispose of.
Clean-up methods - small spillage
Use approved industrial vacuum cleaner for removal.
Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion : Keep away from heat and sources of ignition. Take precautionary measures against static discharges. Avoid dust formation.

Advice on safe handling : Provide sufficient air exchange and/or exhaust in work rooms.
Routine housekeeping should be instituted to ensure that dusts do not accumulate on surfaces.
Minimize dust generation and accumulation.
Dry powders can build static electricity charges when subjected to the friction of transfer and mixing operations.
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
Breathing must be protected when large quantities are de-canted without local exhaust ventilation.
Keep container closed when not in use.

Conditions for safe storage : Keep tightly closed in a dry and cool place.
Keep in a well-ventilated place.
Protect from heat and direct sunlight.
Jointless smooth floor

Materials to avoid : Keep away from food, drink and animal feedingstuffs.
Advice on Segregation

Catapres®

Version 1.0 Revision Date: 06/03/2015 MSDS Number: 000000015185 Date of last issue: -
Date of first issue: 06/03/2015

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Components with workplace control parameters**

Components	Basis	Factor	Catergory	Values	Remark
2,6-Dichloro-N-(2-imidazolidinylidene)b enzamine Hydrochloride 4205-91-8	ECL		3B	2 µg/m ³	
	BIPC		1b		
ECL (BIPI Exposure Control Limit)					

Contains no substances with occupational exposure limit values.

Engineering measures : It is recommended that all dust control equipment such as local exhaust ventilation and material transport systems involved in handling of this product contain explosion relief vents or an explosion suppression system or an oxygen deficient environment.
Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).
Use only appropriately classified electrical equipment and powered industrial trucks.

Personal protective equipment

Respiratory protection : Use breathing apparatus if exposed to vapours/dust/aerosol.
half mask (EN 140)
particle filter P2

Hand protection Material : Chemical resistant gloves made of butyl rubber or nitrile rubber category III according to EN 374.
Directive : Protective gloves against chemicals and micro-organisms

Eye protection : Safety glasses with side-shields

Skin and body protection : Laboratory: laboratory coat; factory: disposable Overall.

Protective measures : Handle in accordance with good industrial hygiene and safety practice.
Do not breathe dust.
Avoid contact with skin, eyes and clothing.
Only use protective equipment in accordance with national/international regulations. Follow the national regulations about wearing personal protective equipment and the warranty given by the manufacturer for the safe function.

Hygiene measures : General industrial hygiene practice.
Wash hands and face before breaks and immediately after handling the product.
Keep working clothes separately.

Catapres®

Version 1.0 Revision Date: 06/03/2015 MSDS Number: 000000015185 Date of last issue: -
Date of first issue: 06/03/2015

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: solid
Colour	: No data available
Odour	: No data available
Odour Threshold	: No data available
pH	: No data available
Melting point/range	: No data available
Boiling point/boiling range	: Not applicable
Flash point	: Not applicable
Evaporation rate	: No data available
Flammability (solid, gas)	: No data available
Upper explosion limit	: No data available
Lower explosion limit	: No data available
Vapour pressure	: Not applicable
Relative vapour density	: No data available
Relative density	: No data available
Solubility(ies) Water solubility	: No data available
Partition coefficient: n- octanol/water	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity Viscosity, dynamic	: Not applicable
Explosive properties	: No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	: No dangerous reaction known under conditions of normal use.
Chemical stability	: No decomposition if stored and applied as directed.

Catapres®

Version 1.0 Revision Date: 06/03/2015 MSDS Number: 000000015185 Date of last issue: -
Date of first issue: 06/03/2015

Possibility of hazardous reactions : No dangerous reaction known under conditions of normal use.

Conditions to avoid : Extremes of temperature and direct sunlight.

Incompatible materials : No data available

Hazardous decomposition products : No data available

SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity**

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: > 10 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:**Clonidine hydrochloride:**

Acute oral toxicity : LD50 (Rat): = 71 - 775 mg/kg
LD50 (Mouse): = 58 - 352 mg/kg

Acute inhalation toxicity : LC50 (Rat): = 19,7 mg/m³
Exposure time: 4 h

Acute dermal toxicity : Remarks: Dermal absorption possible

Skin corrosion/irritation

Not classified based on available information.

Components:**Clonidine hydrochloride:**

Species: Rabbit
Result: Mild skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:**Clonidine hydrochloride:**

Species: Rabbit
Result: No eye irritation

Catapres®

Version 1.0 Revision Date: 06/03/2015 MSDS Number: 000000015185 Date of last issue: -
Date of first issue: 06/03/2015

Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.
Respiratory sensitisation: Not classified based on available information.

Components:**Clonidine hydrochloride:**

Test Type: Maximisation Test (GPMT)
Species: Guinea pig
Result: Did not cause sensitisation on laboratory animals.

Germ cell mutagenicity

Not classified based on available information.

Components:**Clonidine hydrochloride:**

Genotoxicity in vitro : Test Type: Ames-test
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse
Result: negative

Carcinogenicity

Not classified based on available information.

Components:**Clonidine hydrochloride:**

Remarks: Did not show carcinogenic effects in animal experiments.

IARC No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

NTP No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Not classified based on available information.

Product:

Effects on fertility : Test Type: Study for Effects on Embryo-Fetal Development
Species: Rabbit
Application Route: Oral
NOAEL: 0.045 mg/kg,
Remarks: The value is given in analogy to the following substances:

Test Type: Pre- and Postnatal development study

Catapres®

Version 1.0 Revision Date: 06/03/2015 MSDS Number: 000000015185 Date of last issue: -
Date of first issue: 06/03/2015

Species: Rat
NOAEL: 0.075 mg/kg,
Remarks: The value is given in analogy to the following substances:

Effects on foetal development : Remarks: No data available

STOT - single exposure

Causes damage to organs (Cardio-vascular system, Central nervous system) in contact with skin.

Components:**Clonidine hydrochloride:**

Exposure routes: Skin contact

Target Organs: Cardio-vascular system, Central nervous system

Assessment: The substance or mixture is classified as specific target organ toxicant, single exposure, category 1., The substance or mixture is classified as specific target organ toxicant, single exposure, category 2.

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity**Components:****Clonidine hydrochloride:**

Species: Rat

NOAEL: 0.025 mg/kg

Application Route: Oral

Exposure time: 18 months

Species: Rat

NOAEL: 0.1 mg/kg

Application Route: Oral

Exposure time: 18 months

Species: Rabbit

NOAEL: 0.01 mg/kg

Application Route: intravenous

Exposure time: 28-day

Species: dog

NOAEL: 0.03 mg/kg

Application Route: Oral

Exposure time: 52 weeks

Aspiration toxicity

Not classified based on available information.

Components:**Clonidine hydrochloride:**

No data available

Catapres®

Version 1.0 Revision Date: 06/03/2015 MSDS Number: 000000015185 Date of last issue: -
Date of first issue: 06/03/2015

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Clonidine hydrochloride:**

- Toxicity to fish : Remarks: No data available
- Toxicity to daphnia and other aquatic invertebrates : Remarks: No data available
- Toxicity to algae : Remarks: No data available
- Toxicity to fish (Chronic toxicity) : Remarks: No data available
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): ≥ 0.1 mg/l
Exposure time: 21 d
- Toxicity to bacteria : Remarks: No data available

Persistence and degradability**Product:**

- Biodegradability : Result: Not readily biodegradable.
Remarks: The value is given in analogy to the following substances:

Bioaccumulative potential**Product:**

- Bioaccumulation : Remarks: An appreciable bioaccumulation potential is to be expected ($\log P(o/w) > 3$).
The value is given in analogy to the following substances:

Components:**Clonidine hydrochloride:**

- Partition coefficient: n-octanol/water : $\log P_{ow}$: 2.35

Mobility in soil**Product:**

- Distribution among environmental compartments : Remarks: No data available

Other adverse effects**Product:**

- Results of PBT and vPvB assessment : Non-classified vPvB substance Non-classified PBT substance
- Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Pro-

Catapres®

Version	Revision Date:	MSDS Number:	Date of last issue: -
1.0	06/03/2015	000000015185	Date of first issue: 06/03/2015

tection of Stratospheric Ozone - CAA Section 602 Class I Substances
Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

- Waste from residues : Dispose of in accordance with local regulations.
- Contaminated packaging : Packs that cannot be cleaned should be disposed of in the same manner as the contents.
Uncontaminated packaging can be recycled.
-

SECTION 14. TRANSPORT INFORMATION**International Regulation****Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable for product as supplied.

National Regulations

SECTION 15. REGULATORY INFORMATION**EPCRA - Emergency Planning and Community Right-to-Know Act**

- SARA 311/312 Hazards** : No SARA Hazards
- SARA 302** : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.
- SARA 313** : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM I Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

Catapres®

Version 1.0 Revision Date: 06/03/2015 MSDS Number: 000000015185 Date of last issue: -
Date of first issue: 06/03/2015

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

Massachusetts Right To Know

No components are subject to the Massachusetts Right to Know Act.

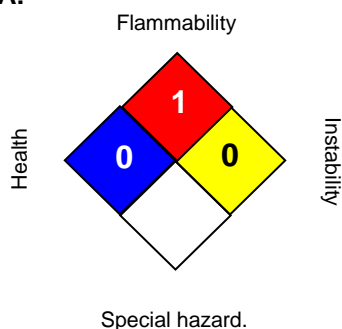
Pennsylvania Right To Know

Non-hazardous galenic excipients Not Assigned 90 - 100 %

New Jersey Right To Know

Non-hazardous galenic excipients Not Assigned 90 - 100 %
Clonidine hydrochloride 4205-91-8 1 - 5 %

California Prop 65 : This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

SECTION 16. OTHER INFORMATION**Further information****NFPA:****HMIS III:**

HEALTH	0
FLAMMABILITY	1
PHYSICAL HAZARD	0

0 = not significant, 1 = Slight,
2 = Moderate, 3 = High
4 = Extreme, * = Chronic

Vertical lines in the left hand margin indicate an amendment from the previous version. Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling. Sources of key data used to compile the Safety Data Sheet : The specifications are based on own tests and/or literature data.

Revision Date : 06/03/2015

The information provided in this Safety Data Sheet 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 guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered 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 materials or in any process, unless specified in the text.

SAFETY DATA SHEET



Catapres®

Version	Revision Date:	MSDS Number:	Date of last issue: -
1.0	06/03/2015	000000015185	Date of first issue: 06/03/2015
