

**Catapres-TTS® Patches**

Version 1.1      Revision Date: 06/03/2015      MSDS Number: 000000042293      Date of last issue: 05/28/2015  
Date of first issue: 05/28/2015

---

**SECTION 1. IDENTIFICATION**

Product name : Catapres-TTS® Patches  
Synonyms : Active ingredient: Clonidine 2%  
Catapres-TTS®-1 Patches; Catapres-TTS®-2 Patches  
Product code : 000000042293

**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](mailto:EHS-service@boehringer-ingelheim.com)

---

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

Specific target organ toxicity : Category 2 (Central nervous system, Cardio-vascular system)  
- single exposure  
Acute toxicity (Oral) : Category 4

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

Hazard pictograms : 

Signal word : Warning  
Hazard statements : H371 May cause damage to organs.  
H302 Harmful if swallowed.  
Precautionary statements : **Prevention:**  
P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.

**Catapres-TTS® Patches**

Version 1.1      Revision Date: 06/03/2015      MSDS Number: 000000042293      Date of last issue: 05/28/2015  
Date of first issue: 05/28/2015

---

**Response:**

P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER/doctor/?.

P330 Rinse mouth.

P308 IF exposed or concerned:

P311 Call a POISON CENTER or doctor/ physician.

**Storage:**

P405 Store locked up.

**Disposal:**

P501 Dispose of contents/ container to an approved incineration plant.

**Other hazards**

None known.

---

**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Hazardous components**

Chemical Name	CAS-No.	Concentration (%)
Clonidine	4205-90-7	2

**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 : No hazards anticipated.

In case of skin contact : Wash off immediately with plenty of water.  
Call a physician immediately.

In case of eye contact : Rinse immediately with plenty of water for at least 15 minutes.  
Keep eye wide open while rinsing.  
Call a physician immediately.

If swallowed : No hazards anticipated.

Most important symptoms and effects, both acute and delayed : None known.

---

**SECTION 5. FIREFIGHTING MEASURES**

**Catapres-TTS® Patches**

Version	Revision Date:	MSDS Number:	Date of last issue: 05/28/2015
1.1	06/03/2015	000000042293	Date of first issue: 05/28/2015

---

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Water  
Dry chemical  
Foam  
Carbon dioxide (CO<sub>2</sub>)
- 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
- Further information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains.  
Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.
- 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.
- Environmental precautions : Do not flush into surface water or sanitary sewer system.
- Methods and materials for containment and cleaning up : Wear personal protective equipment.  
Use mechanical handling equipment.  
Keep in suitable, closed containers for disposal.
- 

**SECTION 7. HANDLING AND STORAGE**

- Advice on protection against fire and explosion : No special protective measures against fire required.
- Advice on safe handling : Provide sufficient air exchange and/or exhaust in work rooms.  
Keep container closed when not in use.
- Conditions for safe storage : Store in original container.  
Protect from heat and direct sunlight.  
Jointless smooth floor  
Keep container tightly closed.
- Materials to avoid : Keep away from food, drink and animal feedingstuffs.  
Advice on Segregation
- 

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

**Catapres-TTS® Patches**

Version 1.1      Revision Date: 06/03/2015      MSDS Number: 000000042293      Date of last issue: 05/28/2015  
 Date of first issue: 05/28/2015

Components	Basis	Factor	Category	Values	Remark
2,6-Dichloro-N-2-imidazolidinylidene-benzenamine 4205-90-7	ECL		3B	2 µg/m <sup>3</sup>	
	BIPC		1b		
ECL (BIPI Exposure Control Limit)					

Contains no substances with occupational exposure limit values.

**Engineering measures** : Local exhaust

**Personal protective equipment**

Respiratory protection : No personal respiratory protective equipment normally required.  
 Respirator must be worn if exposed to dust.  
 half mask (EN 140)  
 particle filter P2

Hand protection Material : Nitrile rubber  
 Break through time : 480 min  
 Glove thickness : 0.43 mm  
 Directive : Protective gloves against chemicals and micro-organisms  
 Protective index : Class 6

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.  
 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.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : Solid form  
 Colour : No data available  
 Odour : odourless

**Catapres-TTS® Patches**

Version 1.1      Revision Date: 06/03/2015      MSDS Number: 000000042293      Date of last issue: 05/28/2015  
Date of first issue: 05/28/2015

---

Odour Threshold : No data available

pH : No data available

Melting point/range : Not applicable

Boiling point/boiling range : Not applicable

Flash point : Not applicable

Evaporation rate : Not applicable

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 : Not applicable

Relative density : No data available

Bulk 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 : Not applicable

---

**SECTION 10. STABILITY AND REACTIVITY**

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

**Catapres-TTS® Patches**

Version 1.1      Revision Date: 06/03/2015      MSDS Number: 000000042293      Date of last issue: 05/28/2015  
Date of first issue: 05/28/2015

---

**SECTION 11. TOXICOLOGICAL INFORMATION****Acute toxicity**

Harmful if swallowed.

**Product:**

Acute oral toxicity : Acute toxicity estimate: 1,000 - 2,000 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:**

Acute oral toxicity : LD50 (Rat): = 157 - 465 mg/kg  
LD50 (Mouse): = 108 - 392 mg/kg  
LD50 (dog): > 15 - < 60 mg/kg

Acute inhalation toxicity : LC50 (Rat): = 19,7 mg/m<sup>3</sup>  
Exposure time: 4 h

Acute dermal toxicity : Remarks: Dermal absorption possible

**Skin corrosion/irritation**

Not classified based on available information.

**Components:****Clonidine:**

Species: Rabbit  
Assessment: No skin irritation  
Result: Mild skin irritation

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****Clonidine:**

Species: Rabbit  
Result: No eye irritation  
Assessment: No eye irritation

**Respiratory or skin sensitisation**

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

**Catapres-TTS® Patches**

Version	Revision Date:	MSDS Number:	Date of last issue: 05/28/2015
1.1	06/03/2015	000000042293	Date of first issue: 05/28/2015

---

**Components:****Clonidine:**

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:**

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:**

Remarks: Did not show carcinogenic effects in animal experiments.

<b>IARC</b>	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.
-------------	---

<b>OSHA</b>	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.
-------------	---

<b>NTP</b>	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.

**STOT - single exposure**

Not classified based on available information.

**Components:****Clonidine:**

Exposure routes: Skin contact

Target Organs: Central nervous system, Cardio-vascular system

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

**STOT - repeated exposure**

Not classified based on available information.

**Catapres-TTS® Patches**

Version 1.1      Revision Date: 06/03/2015      MSDS Number: 000000042293      Date of last issue: 05/28/2015  
Date of first issue: 05/28/2015

---

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

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:**

No data available

---

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

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)):  $\geq 0.1$  mg/l  
Exposure time: 21 d

Toxicity to bacteria : Remarks: No data available



**Catapres-TTS® Patches**

Version 1.1      Revision Date: 06/03/2015      MSDS Number: 000000042293      Date of last issue: 05/28/2015  
Date of first issue: 05/28/2015

---

**Persistence and degradability**

No data available

**Bioaccumulative potential****Components:****Clonidine:**

Partition coefficient: n-octanol/water : Remarks: No data available

**Mobility in soil**

No data available

**Other adverse effects****Product:**Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Protection 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** : Acute Health Hazard**SARA 302** : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

**Catapres-TTS® Patches**

Version	Revision Date:	MSDS Number:	Date of last issue: 05/28/2015
1.1	06/03/2015	000000042293	Date of first issue: 05/28/2015

---

**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.

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 %
----------------------------------	--------------	------------

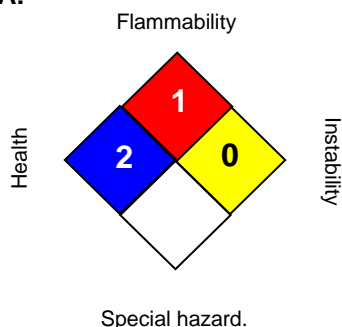
**New Jersey Right To Know**

Non-hazardous galenic excipients	Not Assigned	90 - 100 %
Clonidine	4205-90-7	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.

**Catapres-TTS® Patches**

Version 1.1      Revision Date: 06/03/2015      MSDS Number: 000000042293      Date of last issue: 05/28/2015  
 Date of first issue: 05/28/2015

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

<b>HEALTH</b>	<b>2</b>
<b>FLAMMABILITY</b>	<b>1</b>
<b>PHYSICAL HAZARD</b>	<b>0</b>

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.