SAFETY DATA SHEET

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

SECTION 2. HAZARDS IDENTIFICATION

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

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.
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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS-No.</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clonidine</td>
<td>4205-90-7</td>
<td>2</td>
</tr>
</tbody>
</table>

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
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

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.


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
Components | Basis | Factor | Category | Values | Remark
--- | --- | --- | --- | --- | ---
2,6-Dichloro-N-2-imidazolidinylidene-benzenamine 4205-90-7 | ECL | | 3B | | 2 µg/m³
| BIPC | | 1b | | |

ECL (BIP) 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
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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
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/m3
   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.
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.

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.

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.
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

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**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)): >= 0.1 mg/l  
  Exposure time: 21 d
- Toxicity to bacteria: Remarks: No data available
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.
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 SOCMI 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. Clean Water Act, Section 311, Table 116.4A. This product does not contain any Hazardous Chemicals listed under the U.S. Clean Water 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.
SECTION 16. OTHER INFORMATION

Further information

NFPA:

<table>
<thead>
<tr>
<th>Health</th>
<th>Flammability</th>
<th>Instability</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

Special hazard.

HMIS III:

<table>
<thead>
<tr>
<th>HEALTH</th>
<th>FLAMMABILITY</th>
<th>PHYSICAL HAZARD</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

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.