SECTION 1. IDENTIFICATION

Product name : Micardis®

Synonyms : Active ingredient: Telmisartan < 25%
Micardis® Tablets 20mg, 40mg, and 80mg

Product code : 000000010279

Manufacturer or supplier’s details
Company name of supplier : Boehringer-Ingeheim 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

Serious eye damage : Category 1

Hazard pictograms :

Signal word : Danger
Hazard statements : H318 Causes serious eye damage.
Precautionary statements : Prevention:
P280 Wear eye protection/ face protection.
Response:
P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON
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>Meglumin</td>
<td>6284-40-8</td>
<td>&lt; 25</td>
</tr>
<tr>
<td>Telmisartan</td>
<td>144701-48-4</td>
<td>&lt; 25</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: Move to fresh air.
Call a physician immediately.

In case of skin contact: Wash off immediately with plenty of water.
Cover wound with sterile dressing.
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: Rinse mouth.
Drink plenty of water.
Call a physician immediately.

Most important symptoms and effects, both acute and delayed: Causes serious eye damage.

Notes to physician: Observe the summary of product characteristics of proprietary medicinal products

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
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.
- Never return spills in original containers for re-use.

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 decanted 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

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>Basis</th>
<th>Factor</th>
<th>Category</th>
<th>Values</th>
<th>Remark</th>
</tr>
</thead>
<tbody>
<tr>
<td>4'-(2-n-Propyl-4-methyl-6-(1-methylbenzimidazol-2-yl)-benzimidazol-1-yl)methyl)biphenyl-2-carboxylic acid 144701-48-4</td>
<td>ECL</td>
<td>2</td>
<td>1b</td>
<td>100 µg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td>BIPC</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>ECL (BIPI Exposure Control Limit)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Components</th>
<th>Basis</th>
<th>Factor</th>
<th>Category</th>
<th>Values</th>
<th>Remark</th>
</tr>
</thead>
<tbody>
<tr>
<td>D-(-)-1-Desoxy-1-methylaminosoritol 6284-40-8</td>
<td>ECL</td>
<td>1</td>
<td>1a</td>
<td>1,265 µg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td>BIPC</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>ECL (BIPI Exposure Control Limit)</td>
</tr>
</tbody>
</table>

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**: 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: 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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: solid
Colour: white
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 : 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 tested
Oxidizing 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.
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

Components:
Meglumin:
<table>
<thead>
<tr>
<th><strong>Acute oral toxicity</strong></th>
<th>LD50 (Rat): &gt; 5,000 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Acute inhalation toxicity</strong></td>
<td>Remarks: No data available</td>
</tr>
<tr>
<td><strong>Acute dermal toxicity</strong></td>
<td>Remarks: No data available</td>
</tr>
<tr>
<td><strong>Telmisartan:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Acute oral toxicity</strong></td>
<td>LD50 (Rat): &gt; 2,000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>LD50 (dog): &gt; 2,000 mg/kg</td>
</tr>
<tr>
<td><strong>Acute inhalation toxicity</strong></td>
<td>Remarks: No data available</td>
</tr>
<tr>
<td><strong>Acute dermal toxicity</strong></td>
<td>Remarks: No data available</td>
</tr>
</tbody>
</table>

**Skin corrosion/irritation**
Not classified based on available information.

**Components:**
**Meglumin:**
Species: Rabbit  
Method: OECD Test Guideline 404  
Result: No skin irritation

**Telmisartan:**
Species: Rabbit  
Result: No skin irritation

**Serious eye damage/eye irritation**
Causes serious eye damage.

**Components:**
**Meglumin:**
Species: Rabbit  
Result: Severe eye irritation  
Method: OECD Test Guideline 405

**Telmisartan:**
Remarks: No data available

**Respiratory or skin sensitisation**
Skin sensitisation: Not classified based on available information.  
Respiratory sensitisation: Not classified based on available information.

**Components:**
**Meglumin:**
Species: Guinea pig  
Result: No alert for skin sensitization

**Telmisartan:**
Method: DEREK  
Result: No alert for skin sensitization
**Germ cell mutagenicity**
Not classified based on available information.

**Components:**

**Meglumin:**
Genotoxicity in vitro: Test Type: Ames-test  
Species: Salmonella typhimurium  
Result: negative

Genotoxicity in vivo: Remarks: No data available

**Telmisartan:**
Genotoxicity in vitro: Test Type: Ames-test  
Species: Salmonella typhimurium  
Result: negative  
Method: OECD Test Guideline 471

: Test Type: HGPRT assay  
Species: V79 cells (Chinese hamster)  
Result: negative

: Test Type: Chromosomal aberration test  
Species: Human lymphocytes  
Result: negative

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

**Carcinogenicity**
Not classified based on available information.

**Components:**

**Meglumin:**
Remarks: No data available

**Telmisartan:**
Species: Rat  
Exposure time: 104 weeks  
Dose: 100 mg/kg  
Remarks: Did not show carcinogenic effects in animal experiments.

Species: Mouse  
Exposure time: 104 weeks  
Dose: 1000 mg/kg  
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 carcino- gen 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 : Remarks: Experiments have shown no reproductive toxicity effects on laboratory animals.

Effects on foetal development : Remarks: Did not show teratogenic effects in animal experiments
The value is given in analogy to the following substances:

Components:
Meglumin:
Effects on fertility : Remarks: No data available

Effects on foetal development : Remarks: No data available

STOT - single exposure
Not classified based on available information.

Components:
Meglumin:
Remarks: No data available

STOT - repeated exposure
Not classified based on available information.

Components:
Meglumin:
Remarks: No data available

Repeated dose toxicity

Components:
Meglumin:
Species: Rat
NOAEL: 1,000 mg/kg
Application Route: Oral
Exposure time: 26 weeks

Species: dog
NOAEL: 1,000 mg/kg
Application Route: Oral
Exposure time: 52 weeks

Telmisartan:
Species: Rat, male  
NOAEL: = 4 mg/kg  
Application Route: Oral  
Exposure time: 13 weeks  

Species: Rat, female  
NOAEL: = 8 mg/kg  
Application Route: Oral  
Exposure time: 13 weeks  

Species: dog  
NOAEL: = 5 mg/kg  
Application Route: Oral  
Exposure time: 52 weeks  

Aspiration toxicity  
Not classified based on available information.

Components:  
Meglumin:  
No data available  

Telmisartan:  
No data available

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Meglumin:  
Toxicity to fish: LC50 (Brachydanio rerio (zebrafish)): > 1,000 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203  

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 100.1 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202  

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): Remarks: No data available  

Toxicity to bacteria: EC10 (Pseudomonas putida): > 469 mg/l  
Exposure time: 16 h  
Method: Test on inhibition of cell reproduction, B+K
### Telmisartan:

#### Toxicity to fish

<table>
<thead>
<tr>
<th>End point</th>
<th>Concentration</th>
<th>Exposure time</th>
<th>Test Type</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC50 (Oncorhynchus mykiss (rainbow trout))</td>
<td>3.74 mg/l</td>
<td>96 h</td>
<td>static test</td>
<td>OECD Test Guideline 203</td>
</tr>
<tr>
<td>Lowest Observed Effect Concentration (Oncorhynchus mykiss (rainbow trout))</td>
<td>1.92 mg/l</td>
<td>96 h</td>
<td>static test</td>
<td>OECD Test Guideline 203</td>
</tr>
</tbody>
</table>

#### Toxicity to daphnia and other aquatic invertebrates

<table>
<thead>
<tr>
<th>End point</th>
<th>Concentration</th>
<th>Exposure time</th>
<th>Test Type</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC50 (Daphnia (water flea))</td>
<td>18 mg/l</td>
<td>48 h</td>
<td>static test</td>
<td>OECD Test Guideline 203</td>
</tr>
<tr>
<td>NOEC (Daphnia (water flea))</td>
<td>5.4 mg/l</td>
<td>48 h</td>
<td>static test</td>
<td>OECD Test Guideline 203</td>
</tr>
</tbody>
</table>

#### Toxicity to algae

<table>
<thead>
<tr>
<th>End point</th>
<th>Concentration</th>
<th>Exposure time</th>
<th>Test Type</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC50 (Desmodesmus subspicatus)</td>
<td>9.875 mg/l</td>
<td>72 h</td>
<td>OECD Test Guideline 201</td>
<td></td>
</tr>
<tr>
<td>EC50 (Desmodesmus subspicatus)</td>
<td>1.754 mg/l</td>
<td>72 h</td>
<td>OECD Test Guideline 201</td>
<td></td>
</tr>
</tbody>
</table>

#### Toxicity to fish (Chronic toxicity)

<table>
<thead>
<tr>
<th>End point</th>
<th>Concentration</th>
<th>Exposure time</th>
<th>Test Type</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOEC (mummichog)</td>
<td>1.0 mg/l</td>
<td>semi-static</td>
<td>OECD Test Guideline 210</td>
<td></td>
</tr>
<tr>
<td>Lowest Observed Effect Concentration (mummichog)</td>
<td>3.1 mg/l</td>
<td>semi-static</td>
<td>OECD Test Guideline 210</td>
<td></td>
</tr>
</tbody>
</table>

#### Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

<table>
<thead>
<tr>
<th>End point</th>
<th>Concentration</th>
<th>Exposure time</th>
<th>Test Type</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOEC (Daphnia (water flea))</td>
<td>1.2 mg/l</td>
<td>21 d</td>
<td>semi-static</td>
<td>OECD Test Guideline 211</td>
</tr>
<tr>
<td>Lowest Observed Effect Concentration (Daphnia (water flea))</td>
<td>3.9 mg/l</td>
<td>21 d</td>
<td>semi-static</td>
<td>OECD Test Guideline 211</td>
</tr>
<tr>
<td>NOEC (Chironomus riparius)</td>
<td>500 mg/kg</td>
<td>27 d</td>
<td>semi-static</td>
<td>OECD Test Guideline 211</td>
</tr>
</tbody>
</table>
Exposure time: 27 d
Test Type: semi-static test

Toxicity to bacteria: NOEC (activated sludge): = 1,000 mg/l
Exposure time: 3 h
Method: Activated Sludge, Respiration Inhibition Test.

Persistence and degradability

Biodegradability
Result: Not readily biodegradable.
Biodegradation: 7%
Exposure time: 28 d
Remarks: The value is given in analogy to the following substances:

Biodegradation: > 70%
Exposure time: 28 d
Remarks: The value is given in analogy to the following substances:

Components:

Meglumin:
Biodegradability
Result: Not readily biodegradable.
Biodegradation: > 70%
Exposure time: 28 d

Bioaccumulative potential

Bioaccumulation
Remarks: An appreciable bioaccumulation potential is to be expected (log P(o/w) > 3).

Components:

Meglumin:
Bioaccumulation
Remarks: No bioaccumulation is to be expected (log P(o/w)<1).

Partition coefficient: n-octanol/water
log Pow: < 0.9

Telmisartan:
Partition coefficient: n-octanol/water
log Pow: 3.5 (25 °C)
Method: OECD Test Guideline 117

Mobility in soil

Components:

Meglumin:
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 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).

Components:

Meglumin:
Results of PBT and vPvB assessment: Non-classified vPvB substance Non-classified PBT substance

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 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 %
Meglumin 6284-40-8 20 - 30 %
Telmisartan 144701-48-4 20 - 30 %

New Jersey Right To Know
Non-hazardous galenic excipients Not Assigned 90 - 100 %
Meglumin 6284-40-8 20 - 30 %
Telmisartan 144701-48-4 20 - 30 %

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:

FLAMMABILITY: 1
PHYSICAL HAZARD: 0

HMIS III:

HEALTH: 0

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

Special hazard.
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 Manu-
facturing, 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.