

**Micardis®**

Version 1.0      Revision Date: 06/03/2015      MSDS Number: 000000010279      Date of last issue: -  
Date of first issue: 06/03/2015

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**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-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)

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

Serious eye damage : Category 1

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

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

**Micardis®**

Version 1.0      Revision Date: 06/03/2015      MSDS Number: 000000010279      Date of last issue: -  
Date of first issue: 06/03/2015

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CENTER or doctor/ physician.

**Other hazards**

None known.

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

Substance / Mixture : Mixture

**Hazardous components**

Chemical Name	CAS-No.	Concentration (%)
Meglumin	6284-40-8	< 25
Telmisartan	144701-48-4	< 25

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**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
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**SECTION 5. FIREFIGHTING MEASURES**

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
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**Micardis®**

Version	Revision Date:	MSDS Number:	Date of last issue: -
1.0	06/03/2015	000000010279	Date of first issue: 06/03/2015

---

Water  
Foam  
Dry chemical  
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  
Nitrogen oxides (NO<sub>x</sub>)

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.  
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.  
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

**Micardis®**

Version 1.0      Revision Date: 06/03/2015      MSDS Number: 000000010279      Date of last issue: -  
Date of first issue: 06/03/2015

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**

Components	Basis	Factor	Catergory	Values	Remark
4'-((2-n-Propyl-4-methyl-6-(1-methylbenzimidazol-2-yl)-benzimidazol-1-yl)methyl)biphenyl-2-carboxylic acid 144701-48-4	ECL		2	100 µg/m <sup>3</sup>	
	BIPC		1b		
ECL (BIPI Exposure Control Limit)					

Components	Basis	Factor	Catergory	Values	Remark
D-(-)-1-Desoxy-1-methylaminosorbitol 6284-40-8	ECL		1	1,265 µg/m <sup>3</sup>	
	BIPC		1a		
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 : No personal respiratory protective equipment normally required.

**Micardis®**

Version	Revision Date:	MSDS Number:	Date of last issue: -
1.0	06/03/2015	000000010279	Date of first issue: 06/03/2015

---

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

**Micardis®**

Version 1.0      Revision Date: 06/03/2015      MSDS Number: 000000010279      Date of last issue: -  
Date of first issue: 06/03/2015

---

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

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**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

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**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:**

**Micardis®**

Version	Revision Date:	MSDS Number:	Date of last issue: -
1.0	06/03/2015	000000010279	Date of first issue: 06/03/2015

---

Acute oral toxicity : LD50 (Rat): > > 5,000 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

**Telmisartan:**

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg

LD50 (dog): > 2,000 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

**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

**Micardis®**

Version	Revision Date:	MSDS Number:	Date of last issue: -
1.0	06/03/2015	000000010279	Date of first issue: 06/03/2015

---

**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  
Method: OECD Test Guideline 471  
Result: negative

: 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 carcinogen by OSHA.



**Micardis®**

Version 1.0      Revision Date: 06/03/2015      MSDS Number: 000000010279      Date of last issue: -  
Date of first issue: 06/03/2015

---

**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:**

**Micardis®**

Version 1.0      Revision Date: 06/03/2015      MSDS Number: 000000010279      Date of last issue: -  
Date of first issue: 06/03/2015

---

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

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**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

**Micardis®**

Version	Revision Date:	MSDS Number:	Date of last issue: -
1.0	06/03/2015	000000010279	Date of first issue: 06/03/2015

---

**Telmisartan:**

- Toxicity to fish** : LC50 (Oncorhynchus mykiss (rainbow trout)): = 3.74 mg/l  
 Exposure time: 96 h  
 Test Type: static test  
 Method: OECD Test Guideline 203
- Lowest Observed Effect Concentration (Oncorhynchus mykiss (rainbow trout)): = 1.92 mg/l  
 Exposure time: 96 h  
 Test Type: static test  
 Method: OECD Test Guideline 203
- Toxicity to daphnia and other aquatic invertebrates** : EC50 (Daphnia (water flea)): = 18 mg/l  
 Exposure time: 48 h  
 Test Type: static test
- NOEC (Daphnia (water flea)): = 5.4 mg/l  
 Exposure time: 48 h  
 Test Type: static test
- Toxicity to algae** : EC50 (Desmodesmus subspicatus): = 9.875 mg/l  
 End point: Growth rate  
 Exposure time: 72 h  
 Method: OECD Test Guideline 201
- EC50 (Desmodesmus subspicatus): = 1.754 mg/l  
 End point: Biomass  
 Exposure time: 72 h  
 Method: OECD Test Guideline 201
- Toxicity to fish (Chronic toxicity)** : NOEC (mummichog): = 1.0 mg/l  
 Test Type: semi-static test  
 Method: OECD Test Guideline 210
- Lowest Observed Effect Concentration (mummichog): = 3.1 mg/l  
 Test Type: semi-static test  
 Method: OECD Test Guideline 210
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)** : NOEC (Daphnia (water flea)): = 1.2 mg/l  
 Exposure time: 21 d  
 Test Type: semi-static test  
 Method: OECD Test Guideline 211
- Lowest Observed Effect Concentration (Daphnia (water flea)): = 3.9 mg/l  
 Exposure time: 21 d  
 Test Type: semi-static test  
 Method: OECD Test Guideline 211
- NOEC (Chironomus riparius): = 500 mg/kg  
 Exposure time: 27 d  
 Test Type: semi-static test
- Lowest Observed Effect Concentration (Chironomus riparius):

**Micardis®**

Version	Revision Date:	MSDS Number:	Date of last issue: -
1.0	06/03/2015	000000010279	Date of first issue: 06/03/2015

---

= 1,000 mg/l  
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****Product:**

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

Result: Not readily biodegradable.  
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****Product:**

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 :  $\log P_{ow} < 0.9$

**Telmisartan:**

Partition coefficient: n-octanol/water :  $\log P_{ow} > 3.5$  (25 °C)  
Method: OECD Test Guideline 117

**Mobility in soil****Components:****Meglumin:**

Distribution among environmental compartments : Remarks: No data available

**Micardis®**

Version	Revision Date:	MSDS Number:	Date of last issue: -
1.0	06/03/2015	000000010279	Date of first issue: 06/03/2015

---

**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**

**Micardis®**

Version 1.0      Revision Date: 06/03/2015      MSDS Number: 000000010279      Date of last issue: -  
Date of first issue: 06/03/2015

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. 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**

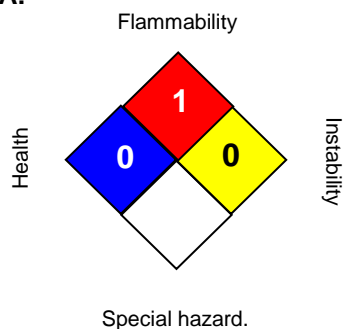
Non-hazardous galenic excipients	Not Assigned	90 - 100 %
Meglumin	6284-40-8	20 - 30 %
Telmisartan	144701-48-4	20 - 30 %

**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:****HMIS III:**

<b>HEALTH</b>	<b>0</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

**Micardis®**

Version	Revision Date:	MSDS Number:	Date of last issue: -
1.0	06/03/2015	000000010279	Date of first issue: 06/03/2015

---

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.