

**Safety data sheet**  
*according to 1907/2006/EC, Article 31*

Printing date 07.10.2020

Version number 2

Revision: 07.10.2020

**SECTION 1: Identification of the substance/mixture and of the company/undertaking**· **1.1 Product identifier**· **Product name:** Irbesartan· **Part number:** Cat 1093· **CAS Number:**  
138402-11-6· **EC number:**  
604-078-2· **1.2 Relevant identified uses of the substance or mixture and uses advised against***No further relevant information available.*· **Application of the substance / the mixture** *Reference material for laboratory use only*· **1.3 Details of the supplier of the safety data sheet**· **Manufacturer/Supplier:**  
British Pharmacopoeia Commission  
MHRA  
10 South Colonnade  
Canary Wharf  
London E14 4PU  
United Kingdom*Tel : +44 (0)20 3080 6561  
eMail: bpcrs@mhra.gov.uk*· **Further information obtainable from:** *eMail: bpcrs@mhra.gov.uk*· **1.4 Emergency telephone number:** +44 (0)20 3080 6561 (Monday - Friday: 8am - 5pm)**SECTION 2: Hazards identification**· **2.1 Classification of the substance or mixture**· **Classification according to Regulation (EC) No 1272/2008**

GHS08 health hazard

*Repr. 1A H360D-H362 May damage the unborn child. May cause harm to breast-fed children.*· **2.2 Label elements**· **Labelling according to Regulation (EC) No 1272/2008***The substance is classified and labelled according to the CLP regulation.*· **Hazard pictograms**

GHS08

· **Signal word** *Danger*· **Hazard statements***H360D-H362 May damage the unborn child. May cause harm to breast-fed children.*· **Precautionary statements***P260 Do not breathe dusts or mists.**P263 Avoid contact during pregnancy and while nursing.**P280 Wear protective gloves/protective clothing/eye protection/face protection.**P308+P313 IF exposed or concerned: Get medical advice/attention.**P405 Store locked up.*

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P501 *Dispose of contents/container in accordance with local/regional/national/international regulations.*

**· Additional information:***Restricted to professional users.***· 2.3 Other hazards****· Results of PBT and vPvB assessment****· PBT:** Not applicable.**· vPvB:** Not applicable.

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**SECTION 3: Composition/information on ingredients****· 3.1 Chemical characterisation: Substances****· CAS No. Description***138402-11-6 Irbesartan***· Identification number(s) None****· EC number: 604-078-2****· RTECS: HM2950270****· Additional information:** *For the wording of the listed hazard phrases refer to section 16.***SECTION 4: First aid measures****· 4.1 Description of first aid measures****· After inhalation:** *Supply fresh air; consult doctor in case of complaints.***· After skin contact:** *Immediately wash with water and soap and rinse thoroughly.***· After eye contact:** *Rinse opened eye for several minutes under running water.***· After swallowing:** *Rinse mouth. Do not induce vomiting.***· 4.2 Most important symptoms and effects, both acute and delayed** *No further relevant information available.***· 4.3 Indication of any immediate medical attention and special treatment needed***No further relevant information available.***SECTION 5: Firefighting measures****· 5.1 Extinguishing media****· Suitable extinguishing agents:** *Use fire extinguishing methods suitable for surrounding conditions.***· 5.2 Special hazards arising from the substance or mixture***Formation of toxic gases is possible during heating or in case of fire.***· 5.3 Advice for firefighters****· Protective equipment:** *Wear self-contained respiratory protective device.***SECTION 6: Accidental release measures****· 6.1 Personal precautions, protective equipment and emergency procedures** *Avoid formation of dust.***· 6.2 Environmental precautions:** *Do not allow to enter sewers/ surface or ground water.***· 6.3 Methods and material for containment and cleaning up:***Dispose of contaminated material as waste according to item 13.***· 6.4 Reference to other sections***See Section 7 for information on safe handling.**See Section 8 for information on personal protection equipment.*

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See Section 13 for disposal information.

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**SECTION 7: Handling and storage**

- **7.1 Precautions for safe handling** Store in cool, dry place in tightly closed receptacles.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**  
Please refer to the manufacturer's certificate for specific storage and transport temperature conditions.  
Store only in the original receptacle unless other advice is given on the CoA.  
Keep container in a well-ventilated place. Keep away from sources of ignition and heat.
- **Information about storage in one common storage facility:** Store away from foodstuffs.
- **Further information about storage conditions:** None.
- **7.3 Specific end use(s)** No further relevant information available.

**SECTION 8: Exposure controls/personal protection**

- **Additional information about design of technical facilities:** No further data; see item 7.
- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:** Not required.
- **Additional information:** Lists used were valid at the time of SDS preparation.
- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
Keep away from foodstuffs, beverages and feed.  
Wash hands before breaks and at the end of work.
- **Respiratory protection:**  
Not required.  
Use suitable respiratory protective device in case of insufficient ventilation.
- **Protection of hands:**  
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.  
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation  
The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374



Protective gloves

- **Material of gloves** Butyl rubber, BR
- **Penetration time of glove material**  
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:** Safety glasses

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### SECTION 9: Physical and chemical properties

#### · 9.1 Information on basic physical and chemical properties

##### · General Information

##### · Appearance:

Form:	Solid
Colour:	Off white
Odour:	Odourless
Odour threshold:	Not determined.

· pH-value: Not applicable.

##### · Change in condition

Melting point/freezing point:	180-184 °C
Initial boiling point and boiling range:	Not determined.

· Flash point: Not applicable.

· Flammability (solid, gas): Not determined.

· Ignition temperature: Not determined.

· Decomposition temperature: Not determined.

· Auto-ignition temperature: Not determined.

· Explosive properties: Not determined.

##### · Explosion limits:

Lower:	Not determined.
Upper:	Not determined.

· Vapour pressure: Not applicable.

· Density: Not determined.

· Relative density: Not determined.

· Vapour density: Not applicable.

· Evaporation rate: Not applicable.

· Solubility in / Miscibility with Dimethyl formamide: Freely soluble. Methylene chloride, Ethanol:: Slightly soluble

· water: Not determined.

· Partition coefficient: n-octanol/water: 1.13 log P

##### · Viscosity:

Dynamic: Not applicable.

Kinematic: Not applicable.

· 9.2 Other information: No further relevant information available.

### SECTION 10: Stability and reactivity

#### · 10.1 Reactivity

Stable under normal conditions.

No further relevant information available.

#### · 10.2 Chemical stability

Stable under normal conditions.

##### · Thermal decomposition / conditions to be avoided:

Formation of toxic gases is possible during heating or in case of fire.

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- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid Heat.**
- **10.5 Incompatible materials:** Strong oxidizing agents.
- **10.6 Hazardous decomposition products:**  
Formation of toxic gases is possible during heating or in case of fire.

### SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
  - **Acute toxicity** Based on available data, the classification criteria are not met.
  - **LD/LC50 values relevant for classification:**
- |      |      |                    |
|------|------|--------------------|
| Oral | LD50 | >2,000 mg/kg (rat) |
|------|------|--------------------|
- **Primary irritant effect:**
  - **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
  - **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
  - **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
  - **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**  
Repr. 1A
  - **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
  - **Carcinogenicity** Based on available data, the classification criteria are not met.
  - **Reproductive toxicity**  
May damage the unborn child. May cause harm to breast-fed children.
  - **STOT-single exposure** Based on available data, the classification criteria are not met.
  - **STOT-repeated exposure** Based on available data, the classification criteria are not met.
  - **Aspiration hazard** Based on available data, the classification criteria are not met.

### SECTION 12: Ecological information

- **12.1 Toxicity**
  - **Aquatic toxicity:**
- |         |                    |
|---------|--------------------|
| LC50/48 | 191 mg/l (daphnia) |
|---------|--------------------|
- **12.2 Persistence and degradability** No further relevant information available.
  - **12.3 Bioaccumulative potential** No further relevant information available.
  - **12.4 Mobility in soil** No further relevant information available.
  - **Additional ecological information:**
  - **General notes:**  
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water  
Do not allow undiluted product to reach ground water, water course or sewage system.
  - **12.5 Results of PBT and vPvB assessment**
  - **PBT:** Not applicable.
  - **vPvB:** Not applicable.
  - **12.6 Other adverse effects** No further relevant information available.

### SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**  
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

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- **European waste catalogue**  
Waste disposal key numbers from EWC have to be assigned depending on origin and processing.
- **Uncleaned packaging:**
- **Recommendation:** Dispose of in accordance with national regulations.

**SECTION 14: Transport information**

- |  |                 |
|--|-----------------|
| · <b>14.1 UN-Number</b>  |                 |
| · <b>ADR, IMDG, IATA</b>   | Not applicable  |
| · <b>ADR, IMDG, IATA</b>   | Not applicable  |
| · <b>14.3 Transport hazard class(es)</b>   |                 |
| · <b>ADR, ADN, IMDG, IATA</b>  |                 |
| · <b>Class</b>   | Not applicable  |
| · <b>14.4 Packing group</b>  |                 |
| · <b>ADR, IMDG, IATA</b>   | Not applicable  |
| · <b>14.5 Environmental hazards:</b>   | Not applicable. |
| · <b>14.6 Special precautions for user</b>                                       | Not applicable. |
| · <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b> | Not applicable. |
| · <b>UN "Model Regulation":</b>  | Not applicable  |

**SECTION 15: Regulatory information**

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** Substance is not listed.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

**SECTION 16: Other information**

The information in this safety data sheet (SDS) has been prepared with due care and is true and accurate to the best of our knowledge. The user must determine the suitability of the information for its particular purpose, ensure compliance with existing laws and regulations, and be aware that other or additional safety or performance considerations may arise when using, handling and/ or storing the material. The information in this SDS does not purport to be all inclusive or a guarantee as to the properties of the material supplied, and should be used only as a guide. British Pharmacopoeia Commission Office makes no warranties or representations as to the accuracy and completeness of the information contained herein, shall not be held responsible for the suitability of this information for the user's intended purposes or the consequences of such use, and shall not be liable for any damage or loss, howsoever arising, direct or otherwise.

**Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)  
IMDG: International Maritime Code for Dangerous Goods  
IATA: International Air Transport Association  
GHS: Globally Harmonised System of Classification and Labelling of Chemicals

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*EINECS: European Inventory of Existing Commercial Chemical Substances**CAS: Chemical Abstracts Service (division of the American Chemical Society)**LC50: Lethal concentration, 50 percent**LD50: Lethal dose, 50 percent**PBT: Persistent, Bioaccumulative and Toxic**vPvB: very Persistent and very Bioaccumulative**Repr. 1A: Reproductive toxicity – Category 1A***· Sources***Tables 3.1 and 3.2 from Annex 6 of EC 1272/2008, EC 1907/2006, EH40/2005 as amended 2011, Registry of Toxic Effects of Chemical Substances (RTECS), The Dictionary of Substances and their Effects, 1st Edition, IUCLID.*

- **Data compared to the previous version altered.** All sections have been updated.

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