

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

Printing date 29.06.2021

Version number 1

Revision: 29.06.2021

SECTION 1: Identification of the substance/mixture and of the company/undertaking· **1.1 Product identifier**· **Product name:** Lisinopril dihydrate Assay Standard· **Part number:** Cat 695· **CAS Number:**
83915-83-7· **EC number:**
627-033-9· **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**

health hazard

Repr. 1A H360 May damage fertility or the unborn child.

· **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**

H360 May damage fertility or the unborn child.

· **Precautionary statements**

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing 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 Substances****· CAS No. Description**

83915-83-7 Lisinopril Dihydrate

· Identification number(s) None**· EC number:** 627-033-9**· RTECS:** TW3589990**· 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

- **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**
- **Appropriate engineering controls** No further data; see item 7.
- **Individual protection measures, such as 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.
- **Hand protection**
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.
- **Eyeface protection** Safety glasses

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SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Physical state	Solid
· Colour:	White
· Odour:	Odourless
· Odour threshold:	Not determined.
· Melting point/freezing point:	175-177 °C
· Boiling point or initial boiling point and boiling range	Not determined.
· Flammability	Not determined.
· Lower and upper explosion limit	
· Lower:	Not determined.
· Upper:	Not determined.
· Flash point:	Not applicable.
· Auto-ignition temperature:	Not determined.
· Decomposition temperature:	Not determined.
· pH	Not applicable.
· Viscosity:	
· Kinematic viscosity	Not applicable.
· Dynamic:	Not applicable.
· Solubility	
· water:	Not determined.
· Partition coefficient n-octanol/water (log value)	0.908 Log Pow
· Vapour pressure:	Not applicable.
· Density and/or relative density	
· Density:	Not determined.
· Relative density	Not determined.
· Vapour density	Not applicable.

· 9.2 Other information

· Appearance:	
· Form:	Solid
· Important information on protection of health and environment, and on safety.	
· Ignition temperature:	Not determined
· Explosive properties:	Not determined.
· Change in condition	
· Evaporation rate	Not applicable.

· Information with regard to physical hazard classes

· Explosives	Not applicable
· Flammable gases	Not applicable
· Aerosols	Not applicable
· Oxidising gases	Not applicable
· Gases under pressure	Not applicable
· Flammable liquids	Not applicable
· Flammable solids	Not applicable
· Self-reactive substances and mixtures	Not applicable
· Pyrophoric liquids	Not applicable
· Pyrophoric solids	Not applicable

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- | | |
|--|----------------|
| · Self-heating substances and mixtures | Not applicable |
| · Substances and mixtures, which emit flammable gases in contact with water | Not applicable |
| · Oxidising liquids | Not applicable |
| · Oxidising solids | Not applicable |
| · Organic peroxides | Not applicable |
| · Corrosive to metals | Not applicable |
| · Desensitised explosives | Not applicable |

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.
- **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 hazard classes as defined in Regulation (EC) No 1272/2008**
- **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.
- **Reproductive toxicity** May damage fertility or the unborn child.
- **Additional toxicological information:**
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
Repr. 1A
- **11.2 Information on other hazards**
- **Endocrine disrupting properties** Substance is not listed.

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **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.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties**
The product does not contain substances with endocrine disrupting properties.

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- **12.7 Other adverse effects**
- **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.

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.
- **Uncleaned packaging:**
- **Recommendation:** Dispose of in accordance with national regulations.

SECTION 14: Transport information

- | | |
|---|-----------------|
| · 14.1 UN number or ID number | |
| · ADR, IMDG, IATA | Not applicable |
| · ADR, IMDG, IATA | Not applicable |
| · 14.3 Transport hazard class(es) | |
| · ADR, ADN, IMDG, IATA | |
| · Class | Not applicable |
| · 14.4 Packing group | |
| · ADR, IMDG, IATA | Not applicable |
| · 14.5 Environmental hazards: | Not applicable. |
| · 14.6 Special precautions for user | Not applicable. |
| · 14.7 Maritime transport in bulk according to IMO instruments | Not applicable. |
| · UN "Model Regulation": | 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,

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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 relatif au transport international 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
EINECS: European Inventory of Existing Commercial Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
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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