

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 03.02.2014

Version number 1

Revision: 03.02.2014

SECTION 1: Identification of the substance/mixture and of the company/undertaking

- **Product identifier**
- **Trade name:** **Trandolapril Impurity E**
- **Reference number:** Cat 1085
- **CAS Number:**
87679-71-8
- **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
- **Manufacturer/Supplier:**
British Pharmacopoeia Commission
MHRA
151 Buckingham Palace Road
London SW1W 9SZ
United Kingdom
Tel : +44 (0)20 3080 6561
eMail: bpcrs@mhra.gsi.gov.uk
- **Further information obtainable from:** eMail: bpcrs@mhra.gsi.gov.uk
- **Emergency telephone number:** +44 (0) 20 3080 6561 (Monday - Friday: 8am - 5pm)

SECTION 2: Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**



GHS08 health hazard

- Repr. 2 H361 Suspected of damaging fertility or the unborn child.
- STOT RE 2 H373 May cause damage to organs through prolonged or repeated exposure.

- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**



T; Toxic

Repr. Cat. 2

R61: May cause harm to the unborn child.



Xn; Harmful

R62-48/20/21/22: Possible risk of impaired fertility. Harmful: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed.

- **Information concerning particular hazards for human and environment:** Not applicable.

- **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** Warning
- **Hazard statements**
H361 Suspected of damaging fertility or the unborn child.
H373 May cause damage to organs through prolonged or repeated exposure.
- **Precautionary statements**
P260 Do not breathe dust/fume/gas/mist/vapours/spray.

(Contd. on page 2)

Safety data sheet

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Version number 1

Revision: 03.02.2014

Trade name: Trandolapril Impurity E

(Contd. from page 1)

- P281 Use personal protective equipment as required.
- P308+P313 IF exposed or concerned: Get medical advice/attention.
- P314 Get medical advice/attention if you feel unwell.
- P405 Store locked up.
- P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

- **Chemical characterization: Substances**
- **CAS No. Description**
87679-71-8 Trandolaprilat Monohydrate
- **Identification number(s)** -
- **Additional information:** For the wording of the listed risk phrases refer to section 16.

SECTION 4: First aid measures

- **Description of first aid measures**
- **General information:**
Symptoms of poisoning may occur even after several hours; therefore medical observation for at least 48 hours after the accident is recommended.
- **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.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

SECTION 5: Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Special hazards arising from the substance or mixture**
Formation of toxic gases is possible during heating or in case of fire.
- **Advice for firefighters**
- **Protective equipment:** Wear self-contained respiratory protective device.

SECTION 6: Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Avoid formation of dust.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Dispose of contaminated material as waste according to item 13.
- **Reference to other sections**
See Section 7 for information on safe handling.

(Contd. on page 3)

Safety data sheet

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Revision: 03.02.2014

Trade name: Trandolapril Impurity E

(Contd. from page 2)

See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

- **Handling:**
- **Precautions for safe handling**
Store in cool, dry place in tightly closed receptacles.
Open and handle receptacle with care.
- **Information about fire - and explosion protection:** Keep respiratory protective device available.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**
Store in a cool location.
Please refer to the manufacturer's certificate for specific storage and transport temperature conditions.
Store only in the original receptacle.
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.
- **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.
- **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.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.
Store protective clothing separately.
- **Respiratory protection:**
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
- **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

(Contd. on page 4)

Safety data sheet

according to 1907/2006/EC, Article 31

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Version number 1

Revision: 03.02.2014

Trade name: Trandolapril Impurity E

(Contd. from page 3)

- **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

SECTION 9: Physical and chemical properties

Information on basic physical and chemical properties**General Information****Appearance:**

· Form:	Solid
· Colour:	Light yellow
· Odour:	Odourless
· Odour threshold:	Not determined.

· **pH-value:** Not applicable.

Change in condition

· Melting point/Melting range:	132-134 °C
· Boiling point/Boiling range:	Not determined.

· **Flash point:** Not applicable.

· **Flammability (solid, gaseous):** Not determined.

Ignition temperature:

· **Decomposition temperature:** Not determined.

· **Self-igniting:** Not determined.

· **Danger of explosion:** 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 water:**

Not determined.

· **Partition coefficient (n-octanol/water):** Not determined.

Viscosity:

· **Dynamic:** Not applicable.

· **Kinematic:** Not applicable.

Other information

No further relevant information available.

SECTION 10: Stability and reactivity

· **Reactivity** Stable under normal conditions.

· **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.

(Contd. on page 5)

Safety data sheet

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Trade name: Trandolapril Impurity E

(Contd. from page 4)

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

SECTION 11: Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** No irritating effect.
- **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
Repr. 2

SECTION 12: Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **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.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

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

- **UN-Number**
- **ADR, ADN, IMDG, IATA** Not applicable
- **ADR, ADN, IMDG, IATA** Not applicable

(Contd. on page 6)

Safety data sheet

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Version number 1

Revision: 03.02.2014

Trade name: Trandolapril Impurity E

(Contd. from page 5)

· Transport hazard class(es)	
· ADR, ADN, IMDG, IATA	
· Class	Not applicable
· Packing group	
· ADR, IMDG, IATA	Not applicable
· Environmental hazards:	
· Marine pollutant:	No
· Special precautions for user	Not applicable.
· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.
· UN "Model Regulation":	-

SECTION 15: Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Philippines Inventory of Chemicals and Chemical Substances** Substance is not listed.
- **Australian Inventory of Chemical Substances** Substance is not listed.
- **Standard for the Uniform Scheduling of Drugs and Poisons** Substance is not listed.
- **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 Harmonized System of Classification and Labelling of Chemicals

CAS: Chemical Abstracts Service (division of the American Chemical Society)

· **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.