

Product Name: Trandolapril
Issued: Aug-22-2016

abbvie
SAFETY DATA SHEET

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

1.1. Product identifier

Product Name: Trandolapril
Synonyms: Trandolaprilat: RU-44403: LU53496
Drug Code Number: 42422

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended use: Pharmaceuticals

1.3. Details of the supplier of the safety data sheet

Supplier: AbbVie Inc.
1 North Waukegan Road
North Chicago, IL 60064
USA
+1-847-932-7900

Manufacturer European: AbbVie Ireland Pharmaceutical Operations
Manorhamilton Road
Sligo
Ireland

Customer Service Telephone: 1-800-255-5162 (US and Canada only)
+1-847-937-7433

E-mail Address: AbbVie.SDS@abbvie.com

1.4. Emergency telephone number

Emergency Telephone: CHEMTREC: 1(800) 424-9300 (in USA and Canada)
or +1-703-527-3887 (international)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

Reproductive toxicity Category 2
Specific target organ systemic toxicity (repeated exposure) Category 2

Classification according to EU Directives 67/548/EEC or 1999/45/EC

Indication of danger: Xn - Harmful
Risk Phrases: R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed
R63 - Possible risk of harm to the unborn child

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2.2. Label elements



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 P281 - Use personal protective equipment as required
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P314 - Get medical advice/attention if you feel unwell
P501 - Dispose of contents/container to an approved waste disposal plant

2.3. Other hazards

Not determined

SECTION 3: Composition/information on ingredients

Chemical Name	Weight-%	EINECS/ELINCS Number	EEC Classification	EU - GHS Substance Classification	REACH Reg. No
Trandolapril 87679-37-6	98-100	NA	Xn, R48/22 R63	STOT RE 2 (H373) Repr. 2 (H361)	No data available

For the full text of the R-phrases mentioned in this Section, see Section 16
For the full text of the H-Statements mentioned in this Section, see Section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

Eye Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Protection of First-aiders: Use personal protective equipment

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4.2 Most important symptoms and effects, both acute and delayed

Signs and Symptoms Clinical data suggests the following: headaches, coughing, decreased blood pressure, diarrhea, rash, abnormal liver function, abnormal kidney function, edema, dizziness. Occupational exposure has resulted in the following: nausea, tremor, headaches.

Medical Conditions Aggravated by Exposure None known from occupational exposure. Data suggest any pre-existing ailments in the following organs: kidney, liver, central nervous system, Pregnancy. cardiovascular system, gastrointestinal system, hematopoietic system

4.3. Indication of any immediate medical attention and special treatment needed

Notes To Physician: Monitor central nervous system and cardiovascular function, as necessary.

Additional Information: When administered during the second or third trimester, ACE inhibitors can cause injury to the fetus.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable Extinguishing Media: Use extinguishing agent suitable for type of surrounding fire

Unsuitable Extinguishing Media: Not determined

5.2. Special hazards arising from the substance or mixture

Special Exposure Hazards: Not determined

Explosivity: Fine dust clouds may form explosive mixtures with air.

5.3. Advice for firefighters

Protective Equipment and Precautions for Firefighters: As in any fire, wear self-contained breathing apparatus and full protective gear

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal Precautions: For personal protection see section 8.

6.2. Environmental precautions

Environmental Precautions: Contain material and prevent release to waterways or soil.

6.3. Methods and material for containment and cleaning up

Methods for Cleaning Up: Recover product and place in an appropriate container for disposal. Clean contaminated surface thoroughly

Incompatibilities: Oxidizers.

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6.4. Reference to other sections

Refer to Sections 8, 12, and 13 for further information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Store according to label instructions.

7.3. Specific end use(s)

Recommended use: Pharmaceuticals

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure limits:

Chemical Name	Employee Exposure Limit	Skin Notation
Trandolapril 87679-37-6	2 mcg/m ³ TWA	None

8.2. Exposure controls

Engineering Controls: Use inside a hood, glovebox or process enclosure.

Respiratory Protection: An approved respirator (i.e. NIOSH, EN, etc.) should be worn when exposures are expected to exceed the applicable limits.

Eyes: Wear eye protection appropriate to handling activities.

Gloves: Impervious gloves.

Other PPE Data: Wear appropriate body coverings if contact may occur.

Environmental Exposure Controls: Not determined

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance: White Crystalline Powder

Odor: Odorless.

Odor Threshold: Not determined

pH: Not determined

Boiling Pt. @ 760 mm Hg (°C): Not determined

Melting/Freezing Point (°C): 125

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Flash Point (°C):	Not determined
Evaporation Rate at 20°C:	Not determined
Flammability (Solid):	Not determined
Lower Explosive Limit:	Not determined
Upper Explosive Limit:	Not determined
Vapor Pressure (mm Hg):	Not determined
Vapor Density (Air = 1):	Not determined
Specific Gravity:	Not determined
Solubility(ies):	Slightly soluble in: water. Soluble in: chloroform, methylene chloride, methanol.
Partition coefficient:	Not determined
n-octanol/water	
Autoignition Temp. (°C):	510
Decomposition temperature (°C):	Not determined
Viscosity (centipoise):	Not determined
Explosion Severity:	Not determined
Oxidizer Properties:	Not determined

9.2. Other information

(Bad file name) (Bad file name)

Maximum Pressure Rise (bar):	7.8
Max. rate of pressure rise (bar/sec):	711
Kst Value (bar.m/s):	193
Min. Ignition Energy-Cloud (mJ):	30-100

SECTION 10: Stability and reactivity

10.1. Reactivity

Not determined

10.2. Chemical stability

Stable under normal conditions

10.3. Possibility of hazardous reactions

Hazardous reactions: Not determined

10.4. Conditions to avoid

Not determined

10.5. Incompatible materials

Oxidizing agents

10.6. Hazardous decomposition products

Carbon oxides, Nitrogen oxides (NOx)

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SECTION 11: Toxicological information

11.1. Information on toxicological effects

Routes of Exposure:

Oral: Yes
Dermal: Yes
Inhalation: Yes

Acute Toxicity - Oral: Data for component (s) given below:

Chemical Name	Acute Test	Value	Units	Species
Trandolapril 87679-37-6	LD50 =	3990 5000 2000	mg/kg	Mice Rats Dogs

Acute Toxicity - Dermal: Not determined

Acute Toxicity - Inhalation: Not determined

Other Toxicology Data: Data for component (s) given below:

Chemical Name	Test Type	Value	Units	Species	Comments
Trandolapril 87679-37-6	LD50 (ip) =	1420 - 1435 1285 - 1330	mg/kg	Rats Mice	None

Corrosivity Not determined

Dermal Irritation: Not determined

Eye irritation Not determined

Sensitization Not considered to be a skin sensitizer.

Toxicokinetics/Metabolism: Not determined

Target Organ Effects Data for component (s) given below:

Chemical Name	Target Organs:	Species	Dosage	Units	Route	Duration
Trandolapril 87679-37-6	Kidney	Rats Dogs	> = 0.25 > 25	mg/kg	Oral	Variable exposure periods

Reproductive Effects In animals adverse reproductive effects include: maternal toxicity.

Data for component (s) given below:

Chemical Name	Species	Dosage	Units	Route	Duration
Trandolapril 87679-37-6	Rabbits	> = 0.4	mg/kg	Oral	During Gestation

Carcinogenicity Not carcinogenic in animal study.

Data for component (s) given below:

Chemical Name	Site of Tumors	Species	Dosage	Route	Units	Duration
Trandolapril 87679-37-6	None	Mice	> 25	Oral Diet	mg/kg	18 months

Mutagenicity: Data for component (s) given below:

Chemical Name	Micronucleus Assay	Ames Test:	Mouse Lymphoma Assay	Chromosomal Abbr. Assay
Trandolapril 87679-37-6	Negative	Negative	Negative	No Data.

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Aspiration hazard: Not determined

Notes:

1. ALD: Approximate lethal dosage
2. LC50: Concentration in air that produces 50% mortality
3. LD50: Oral or dermal dosage that produces 50% mortality

SECTION 12: Ecological information

12.1. Toxicity

Not determined

12.2. Persistence and degradability

Not determined

12.3. Bioaccumulative potential

Not determined

12.4. Mobility in soil

Not determined

12.5. Results of PBT and vPvB assessment

Chemical safety report is not required for this substance/product.

12.6. Other adverse effects

Do not allow undiluted material or large quantities to reach groundwater, bodies of water or sewer system.

Notes:

1. EC50: Concentration in water that produces 50% mortality in *Daphnia* sp.
2. LC50: Concentration in water that produces 50% mortality in fish.
3. EbC50/ErC50: Concentration in water that produces 50% inhibition of growth and in algae.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste Disposal Methods: Disposal should be made in accordance with country, federal, state and local regulations.

SECTION 14: Transport information

ADR, DOT, ICAO/IATA, IMDG/IMO

Status: Not regulated

- | | |
|------------------------------------|----------------|
| 14.1. UN number | Not applicable |
| 14.2. Proper shipping name: | Not applicable |
| 14.3. Hazard class: | Not applicable |
| 14.4. Packing group: | Not applicable |
| 14.5. Environmental hazard: | Not applicable |

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14.6. Special provisions: Not applicable
14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

International Inventories

Chemical Name	EINECS/ ELINCS	TSCA	DSL	NDSL	PICCS
Trandolapril 87679-37-6	-	-	-	Not listed	-

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Trandolapril 87679-37-6	-	Present	-	-	-	

Legend

EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

PICCS - Philippines Inventory of Chemicals and Chemical Substances

ENCS - Japan Existing and New Chemical Substances

ISHL - Japan Industrial Safety and Health Law

IECSC - China Inventory of Existing Chemical Substances

AICS - Australian Inventory of Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

Carcinogenicity Rating:

Chemical Name	Weight-%	NTP:	IARC:	ACGIH:
Trandolapril	98-100	Not listed	Not listed	Not listed

SARA 313 Information

Chemical Name	Weight-%	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Trandolapril	98-100	No	Not applicable	Not applicable

Immediate Health: Yes

Delayed Health: No

Fire: No

Sudden Pressure: No

Reactivity: No

RCRA Status: Not determined

Proposition 65 Status: Does not contain chemicals known to the state of California to cause cancer or reproductive harm.

WHMIS Hazard Class Not determined

NFPA Rating:

Health: 1

Fire: 1

Reactivity: 0

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Notes:

1. SARA = Superfund Amendments and the Reauthorization Act.
2. CERCLA = Comprehensive Environmental Response, Compensation and Liability Act.
3. FIFRA = Federal Insecticide, Fungicide and Rodenticide Act.
4. TSCA = Toxic Substances Control Act.
5. EC = European Community.
6. WHMIS = Canadian Workplace Hazardous Materials Information System.
7. UN GHS = United Nations Globally Harmonized System for Hazard Identification.

15.2. Chemical safety assessment

Chemical safety assessment has not been conducted on the substance/product.

SECTION 16: Other information

Risk Phrases:

R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed

R63 - Possible risk of harm to the unborn child

Full text of H-Statements referred to under sections 2 and 3

H373 - May cause damage to the kidneys/liver/eyes/brain/respiratory system/central nervous system through prolonged or repeated exposure in contact with skin

H361 - Suspected of damaging fertility or the unborn child if inhaled

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