

Product Name: Mavik Tablets
Issued: Jan-02-2013

SAFETY DATA SHEET

Section 1. Identification of the substance/mixture and of the company/undertaking

1.1 Product Identifier

Product Name: Mavik Tablets
Synonyms: Trandolapril tablets: Mavik Tablets, 1 mg; Mavik Tablets, 2 mg; Mavik Tablets, 4 mg
List Number: 2278; 2279; 2280

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: Manufactured for:
AbbVie Inc.
1 North Waukegan Road
North Chicago, IL 60064
USA
1-800-255-5162
+1-847-937-7433
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

2.2 Label elements

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Section 2. Hazards identification



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

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	Percent	EINECS/ELINCS Number	EEC Classification	EU - GHS Substance Classification	REACH No.
Lactose 63-42-3	40-60	200-559-2		Not Hazardous*	No data available
Starch 9005-25-8	30-50	232-679-6		Not Hazardous*	No data available
Povidone 9003-39-8	5-20	NA		Not Hazardous*	No data available
Croscarmellose Sodium 9000-11-7	1-10	NA		Not Hazardous*	No data available
Hydroxypropyl Cellulose 9004-64-2	1-10	NA		Not Hazardous*	No data available
Trandolapril 87679-37-6	1-2.9	NA	Xn, R48/22 R63	STOT RE 2 (H373) Repr. 2 (H361)	No data available

Not Hazardous* - Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System.

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.

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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

4.2 Most important symptoms and effects, both acute and delayed

Signs and Symptoms: None known from occupational exposure. Clinical data suggests the following: headaches, coughing, decreased blood pressure, dizziness, abnormal kidney function, abnormal liver function.

Medical Conditions Aggravated by Exposure: None known from occupational exposure. Data suggest any pre-existing ailments in the following organs: kidney, liver, nervous system, gastrointestinal system, hematopoietic system. Hypersensitivity to the material and/or similar materials.

4.3 Indication of any immediate medical attention and special treatment needed

Notes To Physician: Treat symptomatically

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

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.

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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
Lactose 63-42-3	Not Applicable	None
Starch 9005-25-8	Not Applicable	None
Povidone 9003-39-8	Not Applicable	None
Croscarmellose Sodium 9000-11-7	Not Applicable	None
Hydroxypropyl Cellulose 9004-64-2	Not Applicable	None
Trandolapril 87679-37-6	2 mcg/m ³ TWA	None

Chemical Name	ACGIH TLV	France	German MAK	Ireland	Italy
Lactose 63-42-3	10 mg/m ³ total dust, 3 mg/m ³ respirable dust				
Starch 9005-25-8	10 mg/m ³ total dust for Starch			10 mg/m ³ (TWA) 4 mg/m ³ (TWA) 10 mg/m ³ (TWA)	
Povidone 9003-39-8	10 mg/m ³ for nuisance dust; 3 mg/m ³ respirable particulate				
Croscarmellose Sodium 9000-11-7	10 mg/m ³ as nuisance dust, 3 mg/m ³ for respirable particulate				
Hydroxypropyl Cellulose 9004-64-2	10 mg/m ³ as nuisance dust, for Cellulose				

Chemical Name	The Netherlands	Spain	Switzerland	UK OEL/MEL
Starch 9005-25-8		10 mg/m ³ (TWA)	3 mg/m ³ (TWA)	30 mg/m ³ (STEL) 12 mg/m ³ (STEL) 30 mg/m ³ (STEL) 10 mg/m ³ (TWA) 4 mg/m ³ (TWA)

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8.2. Exposure controls

Engineering Controls: No special provisions are required under normal product use conditions. Use inside a process enclosure when handling the bulk formulation.

Respiratory Protection: Respiratory protection is not needed during normal product use. When handling the bulk formulation, an approved respirator (i.e. NIOSH, EN, etc.) should be worn when exposures are expected to exceed the applicable limits.

Eyes: Eye protection not needed during typical product use conditions. Wear eye protection as appropriate when handling the bulk formulation.

Gloves: Gloves not required during normal product use conditions. Wear impervious gloves when handling the bulk formulation.

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: Tablet

Odor: Odorless.

Odor Threshold: Not determined

pH: Not determined.

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

Melting/Freezing Point (°C): Not determined

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): Not determined.

Partition coefficient: n-octanol/water Not determined.

Autoignition Temp. (°C): Not determined.

Decomposition temperature (°C): Not determined.

Viscosity (centipoise): Not determined.

Explosion Severity: Not determined.

Oxidizer Properties: Not determined.

9.2. Other information

Not determined

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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

Not determined

10.6 Hazardous decomposition products

Carbon oxides, Nitrogen oxides (NO_x)

Section 11. Toxicological information

11.1. Information on toxicological effects

Routes of Exposure:

Oral: Clinical Route
Dermal: Yes
Inhalation: Unlikely

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

Chemical Name	Acute Test	Value	Units	Species
Lactose 63-42-3	LD50 >	10000	mg/kg	Rats
Povidone 9003-39-8	LD50 =	100000 1040	mg/kg	Rats Rabbits
	LD50 >	40000		Mice
Croscarmellose Sodium 9000-11-7	LD50 >	5050	mg/kg	Rats
Hydroxypropyl Cellulose 9004-64-2	LD50 =	5000-10,200	mg/kg	Mice Rats
Trandolapril 87679-37-6	LD50 =	3990 5000 2000	mg/kg	Mice Rats Dogs

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

Chemical Name	Acute Test	Value	Units	Species
Croscarmellose Sodium 9000-11-7	LD50 >	2000	mg/kg	Rabbits

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

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Chemical Name	Test	Value	Units	Species
Croscarmellose Sodium 9000-11-7	LC 50 >	0.13	mg/L , 4 hour	Rats

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: Active Ingredient : Reported to be a non-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: Active Ingredient : In animals adverse reproductive effects include: maternal toxicity.
 Similar Material : In humans adverse reproductive effects include: fetal 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: Active ingredient : 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
Croscarmellose Sodium 9000-11-7	No Data.	Negative	No Data.	Negative
Trandolapril 87679-37-6	Negative	Negative	Negative	No Data.

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

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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 or 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 |
| 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 |

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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
Lactose 63-42-3	200-559-2	X	X	Not listed.	X
Starch 9005-25-8	232-679-6	X	X	Not listed.	X
Povidone 9003-39-8	-	X	X	Not listed.	X
Croscarmellose Sodium 9000-11-7	-	X	X	Not listed.	X
Hydroxypropyl Cellulose 9004-64-2	-	X	X	Not listed.	X
Trandolapril 87679-37-6	-	-	-	Not listed.	-

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Lactose 63-42-3	-	8-(4)-389	X	X	KE-17416	
Starch 9005-25-8	Present	-	X	X	KE-32128	
Povidone 9003-39-8	Present	-	X	X	KE-13324	
Croscarmellose Sodium 9000-11-7	Present	-	X	X	KE-04840	
Hydroxypropyl Cellulose 9004-64-2	Present	-	X	X	KE-05367	
Trandolapril 87679-37-6	-	8-(1)-2308	-	-	-	

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	Percent	NTP:	IARC:	ACGIH:
Lactose	40-60	Not Listed	Not Listed	Not Listed
Starch	30-50	Not Listed	Not Listed	Not Listed
Povidone	5-20	Not Listed	Not Listed	Not Listed
Croscarmellose Sodium	1-10	Not Listed	Not Listed	Not Listed
Hydroxypropyl Cellulose	1-10	Not Listed	Not Listed	Not Listed
Trandolapril	1-2.9	Not Listed	Not Listed	Not Listed

SARA 313 Information

Chemical Name	Percent	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Lactose	40-60	No	Not Applicable	Not applicable
Starch	30-50	No	Not Applicable	Not applicable
Povidone	5-20	No	Not Applicable	Not applicable

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Chemical Name	Percent	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Croscarmellose Sodium	1-10	No	Not Applicable	Not applicable
Hydroxypropyl Cellulose	1-10	No	Not Applicable	Not applicable
Trandolapril	1-2.9	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

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 organs (a,b,c) through prolonged or repeated exposure if inhaled, H361 - Suspected of damaging fertility or the unborn child if inhaled

Document Authored By: Global Occupational Toxicology (D-03QC)

Issued: Jan-02-2013

Supersedes the SDS dated: Oct-25-2001

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