

Product Name: Tarka 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: Tarka Tablets

Synonyms: Tarka (Trandolapril/Verapamil) tablets; Tarka Tablets, 2 mg/180 mg; Tarka Tablets, 1 mg/240 mg; Tarka Tablets, 2 mg/240 mg; Tarka Tablets, 4 mg/240 mg; Tarka Grageas; Tarka Tabletas; Tarka LP

Trade name: Tarka

List Number: 3287; 3288; 3289; 3290; N949

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

Acute oral toxicity	Category 4
Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 2
Specific target organ systemic toxicity (single exposure)	Category 3
Chronic aquatic toxicity	Chronic toxicity 3

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

Indication of danger: Xn - Harmful
Xi - Irritant

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Section 2. Hazards identification

Risk Phrases:

- R22 - Harmful if swallowed
- R36/37/38 - Irritating to eyes, respiratory system and skin
- R52 - Harmful to aquatic organisms
- R53 - May cause long-term adverse effects in the aquatic environment

2.2 Label elements



Signal Word: Warning

Hazard Statements:

- H302 - Harmful if swallowed
- H315 - Causes skin irritation
- H319 - Causes serious eye irritation
- H335 - May cause respiratory irritation
- H412 - Harmful to aquatic life with long lasting effects

P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

P280 - Wear protective gloves/protective clothing/eye protection/face protection

P302 + P352 - IF ON SKIN: Wash with plenty of soap and water

P304 + P340 - IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing

P312 - Call a POISON CENTER or doctor/physician if you feel unwell

P273 - Avoid release to the environment

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.
Sodium Alginate 9005-40-7	20-40	NA		Not Hazardous*	No data available
Verapamil Hydrochloride 152-11-4	20-30	205-800-5	T, R25; Xi, R36/37/38; R52, 53	STOT SE 3 (H335) Skin Irrit. 2 (H315) Eye Irrit. 2 (H319) Acute Tox. 3 (H301) Aquatic Chronic 3 (H412)	No data available

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Section 3. Composition/information on ingredients

Lactose monohydrate 10039-26-6	5-20	NA		Not Hazardous*	No data available
Cellulose Microcrystalline 9004-34-6	1-10	232-674-9		Not Hazardous*	No data available
Starch 9005-25-8	1-10	232-679-6		Not Hazardous*	No data available
Povidone 9003-39-8	1-10	NA		Not Hazardous*	No data available
Water 7732-18-5	1-10	231-791-2		Not Hazardous*	No data available
Titanium Dioxide 13463-67-7	0.1-1	236-675-5		Not Hazardous*	No data available
Trandolapril 87679-37-6	0.1-1	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.

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: nausea, slow heart rate, decreased blood pressure, headaches, fast heart rate, tingling in the extremities, abnormal liver function, abnormal kidney function, edema, dizziness, flushing, numbness, allergic reactions,

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

4.3 Indication of any immediate medical attention and special treatment needed

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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.

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

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Exposure limits:

Chemical Name	Employee Exposure Limit	Skin Notation
Sodium Alginate 9005-40-7	Not Applicable	None
Verapamil Hydrochloride 152-11-4	50 mcg/m ³ TWA	None
Lactose monohydrate 10039-26-6	Not Applicable	None
Cellulose Microcrystalline 9004-34-6	Not Applicable	None
Starch 9005-25-8	Not Applicable	None
Povidone 9003-39-8	Not Applicable	None
Water 7732-18-5	Not Applicable	None
Titanium Dioxide 13463-67-7	Not Applicable	None
Trandolapril 87679-37-6	2 mcg/m ³ TWA	None

Chemical Name	ACGIH TLV	France	German MAK	Ireland	Italy
Sodium Alginate 9005-40-7	10 mg/m ³ , total dust; 3 mg/m ³ respirable particulate				
Cellulose Microcrystalline 9004-34-6	10 mg/m ³ total dust	TWA: 10 mg/m ³		20 mg/m ³ (STEL) 10 mg/m ³ (TWA) 4 mg/m ³ (TWA)	
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				
Titanium Dioxide 13463-67-7	10 mg/m ³ TWA	TWA: 10 mg/m ³		10 mg/m ³ (TWA) 4 mg/m ³ (TWA)	

Chemical Name	The Netherlands	Spain	Switzerland	UK OEL/MEL
Cellulose Microcrystalline 9004-34-6		10 mg/m ³ (TWA)	3 mg/m ³ (TWA)	20 mg/m ³ (STEL) 12 mg/m ³ (STEL) 20 mg/m ³ (STEL) 10 mg/m ³ (TWA) 4 mg/m ³ (TWA)
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)
Titanium Dioxide 13463-67-7		10 mg/m ³ (TWA)	3 mg/m ³ (TWA)	30 mg/m ³ (STEL) 12 mg/m ³ (STEL) 10 mg/m ³ (TWA) 4 mg/m ³ (TWA)

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.

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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:	Oval 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

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.

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10.4. Conditions to avoid

Not determined.

10.5 Incompatible materials

Not determined

10.6 Hazardous decomposition products

Carbon oxides, Nitrogen oxides (NOx)

Section 11. Toxicological information

11.1. Information on toxicological effects

Routes of Exposure:

Oral: Clinical Route
Dermal: Not determined.
Inhalation: Not determined.

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

Chemical Name	Acute Test	Value	Units	Species
Sodium Alginate 9005-40-7	LD50 >	5000	mg/kg	Rats
Verapamil Hydrochloride 152-11-4	LD50 =	108 140 163 >400	mg/kg	Rats Guinea Pigs Mice Dogs
Lactose monohydrate 10039-26-6	LD50 >	10000	mg/kg, for a similar material	Rats
Cellulose Microcrystalline 9004-34-6	LD50 >	5000	mg/kg	Rats
Povidone 9003-39-8	LD50 =	100000 1040 40000	mg/kg	Rats Rabbits Mice
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
Cellulose Microcrystalline 9004-34-6	LD50 >	2000	mg/kg	Rabbits

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

Chemical Name	Test	Value	Units	Species
Cellulose Microcrystalline 9004-34-6	LC 50 >	5800	mg/m ³ , 4 hour	Rats

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

Chemical Name	Test Type	Value	Units	Species	Comments
Verapamil Hydrochloride 152-11-4	LD50 (sc) =	68-107	mg/kg	Mice Rats	None.
Trandolapril 87679-37-6	LD50 (ip) =	1420 - 1435 1285 - 1330	mg/kg	Rats Mice	None.

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Corrosivity: Not determined.

Dermal Irritation: Active Ingredient : May be a skin irritant.

Eye Irritation: Active Ingredient : May be an eye irritant.

Sensitization: Not determined.

Toxicokinetics/Metabolism: Not determined.

Target Organ Effects: Active Ingredient : May cause respiratory tract irritation
Data for component (s) given below.

Chemical Name	Target Organs:	Species	Dosage	Units	Route	Duration
Verapamil Hydrochloride 152-11-4	Eyes	Dogs	60	mg/kg	Oral	12 weeks
Titanium Dioxide 13463-67-7	Lungs	Rats	10,000	mg/L	Inhalation	2 years
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.
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
Titanium Dioxide 13463-67-7	Lungs	Rats	250,000	Inhalation	mg/L	2 years
Trandolapril 87679-37-6	None	Mice	> 25	Oral Diet	mg/kg	18 months

Mutagenicity: Major Ingredient : Negative in the Ames assay. Minor Ingredient : Negative in mutagenicity assays.

Chemical Name	Micronucleus Assay	Ames Test:	Mouse Lymphoma Assay	Chromosomal Abbr. Assay
Verapamil Hydrochloride 152-11-4	No Data.	Negative	No Data.	No Data.
Lactose monohydrate 10039-26-6	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

Data for component (s) given below.

Chemical Name	Percent	LC 50 (mg/l)	Species	Duration
Verapamil Hydrochloride 152-11-4	20-30	> 4.6 < 10	Golden Orfe	96 Hours

12.2. Persistence and degradability

Active ingredient Not readily biodegradable.

Chemical Name	Percent	% Degradation	Duration
Verapamil Hydrochloride 152-11-4	20-30	<20	Unspecified

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

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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

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
Sodium Alginate 9005-40-7	-	-	-	Not listed.	-
Verapamil Hydrochloride 152-11-4	205-800-5	-	X	Not listed.	-
Lactose monohydrate 10039-26-6	-	-	-	Not listed.	-
Cellulose Microcrystalline 9004-34-6	232-674-9	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
Water 7732-18-5	231-791-2	X	X	Not listed.	X
Titanium Dioxide 13463-67-7	236-675-5	X	X	Not listed.	X
Trandolapril 87679-37-6	-	-	-	Not listed.	-

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Sodium Alginate 9005-40-7	-	-	-	-	-	
Verapamil Hydrochloride 152-11-4	-	-	-	X	-	HSR007000
Lactose monohydrate 10039-26-6	-	-	X	-	-	
Cellulose Microcrystalline 9004-34-6	Present	-	X	X	KE-05339	
Starch 9005-25-8	Present	-	X	X	KE-32128	
Povidone 9003-39-8	Present	-	X	X	KE-13324	
Water 7732-18-5	-	-	X	X	KE-35400	
Titanium Dioxide 13463-67-7	Present	-	X	X	KE-33900	
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

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KECL - Korean Existing and Evaluated Chemical Substances

Carcinogenicity Rating:

Chemical Name	Percent	NTP:	IARC:	ACGIH:
Sodium Alginate	20-40	Not Listed	Not Listed	Not Listed
Verapamil Hydrochloride	20-30	Not Listed	Not Listed	Not Listed
Lactose monohydrate	5-20	Not Listed	Not Listed	Not Listed
Cellulose Microcrystalline	1-10	Not Listed	Not Listed	Not Listed
Starch	1-10	Not Listed	Not Listed	Not Listed
Povidone	1-10	Not Listed	Not Listed	Not Listed
Water	1-10	Not Listed	Not Listed	Not Listed
Titanium Dioxide	0.1-1	Not Listed	Not Listed	Not Listed
Trandolapril	0.1-1	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):
Sodium Alginate	20-40	No	Not Applicable	Not applicable
Verapamil Hydrochloride	20-30	No	Not Applicable	Not applicable
Lactose monohydrate	5-20	No	Not Applicable	Not applicable
Cellulose Microcrystalline	1-10	No	Not Applicable	Not applicable
Starch	1-10	No	Not Applicable	Not applicable
Povidone	1-10	No	Not Applicable	Not applicable
Water	1-10	No	Not Applicable	Not applicable
Titanium Dioxide	0.1-1	No	Not Applicable	Not applicable
Trandolapril	0.1-1	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.

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Section 16. Other information

Risk Phrases: R22 - Harmful if swallowed, R36/37/38 - Irritating to eyes, respiratory system and skin, R52 - Harmful to aquatic organisms, R53 - May cause long-term adverse effects in the aquatic environment

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

H301 - Toxic if swallowed, H319 - Causes serious eye irritation, H315 - Causes skin irritation, H335 - May cause respiratory irritation, H412 - Harmful to aquatic life with long lasting effects, 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

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