Issued: May-16-2016

abbvie

SAFETY DATA SHEET

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

1.1. Product identifier

Product Name: Tarka Hard Capsules

Synonyms: Tarka (Trandolapril/Verapamil) Hard Capsules; Tarka capsules; Tarka 2 mg/180

mg Hard Capsule; Tarka Slow Release Capsules

Trade name: Tarka

List Number: N863

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

+1-847-932-7900

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

General Note

Acute oral toxicityCategory 4Skin corrosion/irritationCategory 2Serious eye damage/eyeCategory 2

irritation

Specific target organ systemic Category 3

toxicity (single exposure)

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

Issued: May-16-2016

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

Precautionary Statements 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	Weight-%	EINECS/ELINCS Number	EEC Classification	EU - GHS Substance Classification	REACH Reg. No
Sodium Alginate 9005-40-7	20-40	NA		Not Hazardous*	No data available
Verapamil Hydrochloride 152-11-4	20-30	Present	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)	
Cellulose Microcrystalline 9004-34-6	5-20	Present		Not Hazardous*	No data available
Lactose monohydrate 10039-26-6	5-20	NA		Not Hazardous*	No data available

May-16-2016 Issued:

Kollidon 9003-39-8	1-10	NA		Not Hazardous*	No data available
Starch 9005-25-8	1-10	Present		Not Hazardous*	No data available
Water 7732-18-5	1-10	Present		Not Hazardous*	No data available
Hydroxypropyl Methylcellulose 9004-65-3	1-10	NA		Not Hazardous*	No data available
Titanium Dioxide 13463-67-7	0.1-1	Present		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.

Remove from source of exposure. If signs of toxicity occur, seek medical **Ingestion:**

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:

> Allergic reactions 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,

by Exposure

Medical Conditions Aggravated 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

Notes To Physician: Treat symptomatically

SECTION 5: Firefighting measures

Issued: May-16-2016

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

Exposure limits:

Chemical Name	Employee Exposure Limit	Skin Notation
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Product Name: Tarka Hard Capsules Issued: May-16-2016

Sodium Alginate 9005-40-7	Not applicable	None
Verapamil Hydrochloride 152-11-4	60 mcg/m³ TWA	None
Cellulose Microcrystalline 9004-34-6	Not applicable	None
Lactose monohydrate 10039-26-6	Not applicable	None
Kollidon 9003-39-8	Not applicable	None
Starch 9005-25-8	Not applicable	None
Water 7732-18-5	Not applicable	None
Hydroxypropyl Methylcellulose 9004-65-3	Not applicable	None
Titanium Dioxide 13463-67-7	Not Applicable	None
Trandolapril 87679-37-6	2 mcg/m³ TWA	None

Chemical Name	ACGIH TLV	France	German MAK	Ireland	Italy
Sodium Alginate 9005-40-7	10 mg/m³, total dust; 3 mg/m³ respirable particulate				
Cellulose Microcrystalline 9004-34-6	10 mg/m³ TWA	TWA: 10 mg/m ³		20 mg/m³ (STEL) 12 mg/m³ (STEL) 10 mg/m³ (TWA) 4 mg/m³ (TWA)	
Kollidon 9003-39-8	10 mg/m³ for nuisance dust; 3 mg/m³ respirable particulate				
Starch 9005-25-8	10 mg/m³ TWA			30 mg/m³ (STEL) 12 mg/m³ (STEL) 10 mg/m³ (TWA) 4 mg/m³ (TWA)	
Hydroxypropyl Methylcellulose 9004-65-3	10 mg/m³ total dust; 3 mg/m³ respirable dust				
Titanium Dioxide 13463-67-7	10 mg/m³ TWA	TWA: 10 mg/m ³		30 mg/m³ (STEL) 12 mg/m³ (STEL) 10 mg/m³ (TWA) 4 mg/m³ (TWA)	

Chemical Name	The Netherlands	Spain	Switzerland	UK OEL/MEL
Cellulose Microcrystalline 9004-34-6		10 mg/m³ (TWA)	3 mg/m³ (TWA)	20 mg/m³ (STEL) 12 mg/m³ (STEL) 10 mg/m³ (TWA) 4 mg/m³ (TWA)
Starch 9005-25-8		10 mg/m³ (TWA)	3 mg/m³ (TWA)	30 mg/m³ (STEL) 12 mg/m³ (STEL) 10 mg/m³ (TWA) 4 mg/m³ (TWA)
Titanium Dioxide 13463-67-7		10 mg/m³ (TWA)	3 mg/m³ (TWA)	30 mg/m³ (STEL) 12 mg/m³ (STEL) 10 mg/m³ (TWA) 4 mg/m³ (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.

Issued: May-16-2016

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: Pink Capsule Odor: Not determined **Odor Threshold:** Not determined Not determined pH: **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 Not determined **Partition coefficient:**

n-octanol/water

Autoignition Temp. (°C): Not determined **Decomposition temperature** Not determined

(°C):

Viscosity (centipoise):

Explosion Severity:

Oxidizer Properties:

Not determined

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

Issued: May-16-2016

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 (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
Cellulose Microcrystalline 9004-34-6	LD50 >	5000	mg/kg	Rats
Lactose monohydrate 10039-26-6	LD50 >	10000	mg/kg, for a similar material	Rats
Kollidon 9003-39-8	LD50 = LD50 >	100000 1040 40000	mg/kg	Rats Rabbits Mice
Hydroxypropyl Methylcellulose 9004-65-3	LD50 >	2250	mg/kg	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
Cellulose Microcrystalline	LD50 >	2000	mg/kg	Rabbits
9004-34-6				

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

Chemical Name	Test	Value	Units	Species
Cellulose Microcrystalline	LC 50 >	5800	mg/m³ , 4 hour	Rats
9004-34-6				

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	0 0	Mice Rats	None
Trandolapril 87679-37-6	LD50 (ip) =	1420 - 1435 1285 - 1330	\mathcal{L}	Rats Mice	None

Issued: May-16-2016

Corrosivity Not determined

Dermal Irritation: Active Ingredient(s): 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		Rats Dogs	> = 0.25 > 25	mg/kg	Oral	Variable exposure periods

Reproductive Effects Active Ingredient : In animals adverse reproductive effects include: maternal

toxicity, maternal toxicity.

Data for component (s) given below:

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

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: Data for component (s) given below:

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

SECTION 12: Ecological information

12.1. Toxicity

Data for component (s) given below:

Butti for component (b) given below:					
Chemical Name	Weight-%	LC 50 (mg/l)	Species	Duration	
Verapamil Hydrochloride	20-30	> 4.6 < 10	Golden Orfe	96 Hours	

May-16-2016 **Issued:**

12.2. Persistence and degradability

Active ingredient Not readily biodegradable

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

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

Not regulated **Status:**

Not applicable 14.1. UN number Not applicable 14.2. Proper shipping name: 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 Not applicable

according to Annex II of

MARPOL 73/78 and the IBC

Code:

Issued: May-16-2016

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	Present	-	X	Not listed	-
Cellulose Microcrystalline 9004-34-6	Present	X	X	Not listed	X
Lactose monohydrate 10039-26-6	-	-	-	Not listed	-
Kollidon 9003-39-8	-	X	Х	Not listed	X
Starch 9005-25-8	Present	X	Х	Not listed	X
Water 7732-18-5	Present	X	Х	Not listed	X
Hydroxypropyl Methylcellulose 9004-65-3	-	X	Х	Not listed	X
Titanium Dioxide 13463-67-7	Present	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
Cellulose Microcrystalline 9004-34-6	Present	-	X	X	Present	
Lactose monohydrate 10039-26-6	-	-	X	-	-	
Kollidon 9003-39-8	Present	-	X	X	Present	
Starch 9005-25-8	Present	-	X	X	Present	
Water 7732-18-5	-	-	X	X	Present	
Hydroxypropyl Methylcellulose 9004-65-3	Present	-	X	X	Present	
Titanium Dioxide 13463-67-7	Present	-	X	X	Present	
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:
Sodium Alginate	20-40	Not listed	Not listed	Not listed
Verapamil Hydrochloride	20-30	Not listed	Not listed	Not listed
Cellulose Microcrystalline	5-20	Not listed	Not listed	Not listed

Product Name: Tarka Hard Capsules Issued: May-16-2016

Lactose monohydrate	5-20	Not listed	Not listed	Not listed
Kollidon	1-10	Not listed	Not listed	Not listed
Starch	1-10	Not listed	Not listed	A4 - Not Classifiable as a Human Carcinogen
Water	1-10	Not listed	Not listed	Not listed
Hydroxypropyl Methylcellulose	1-10	Not listed	Not listed	Not listed
Titanium Dioxide	0.1-1	Not listed	Not listed	A4 - Not Classifiable as a Human Carcinogen
Trandolapril	0.1-1	Not listed	Not listed	Not listed

SARA 313 Information

Chemical Name	Weight-%	SARA 313 Chemical:	CERCLA RQ/SARA	SARA EHS TPQ
			EHS RQ (lbs):	(lbs):
Sodium Alginate	20-40	No	Not applicable	Not applicable
Verapamil Hydrochloride	20-30	No	Not applicable	Not applicable
Cellulose Microcrystalline	5-20	No	Not applicable	Not applicable
Lactose monohydrate	5-20	No	Not applicable	Not applicable
Kollidon	1-10	No	Not applicable	Not applicable
Starch	1-10	No	Not applicable	Not applicable
Water	1-10	No	Not applicable	Not applicable
Hydroxypropyl Methylcellulose	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:YesDelayed Health:NoFire:NoSudden Pressure:NoReactivity:No

RCRA Status: Not determined

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

reproductive harm.

Component	Weight-%	Proposition 65 Listed Materials
Titanium Dioxide	0.1-1	carcinogen, 9/2/2011 (airborne, unbound particles
13463-67-7 (0.1-1)		of respirable size)

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

Issued: May-16-2016

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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