

Enalapril Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
7.0	2024/04/06	734745-00017	Date of first issue: 2016/06/07

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name	:	Enalapril Formulation
Supplier's company name, a	ddr	ess and phone number
Company name of supplier	:	Organon & Co.
Address	:	30 Hudson Street, 33nd floor Jersey City, New Jersey, U.S.A 07302
Telephone	:	+1-551-430-6000
E-mail address	:	EHSSTEWARD@organon.com
Emergency telephone number	:	+1-215-631-6999

Recommended use of the chemical and restrictions on use

Recommended use	:	Pharmaceutical
Restrictions on use	:	Not applicable

2. HAZARDS IDENTIFICATION

GHS classification of chemical product Reproductive toxicity : Category 1A					
	Category 2 (Kidney, Cardio-vascular system)				
GHS label elements					
Hazard pictograms					
Signal word	Danger				
Hazard statements	H360D May damage the unborn child. H373 May cause damage to organs (Kidney, Cardio-vascular system) through prolonged or repeated exposure.				
Precautionary statements	 Prevention: P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P260 Do not breathe dust. P280 Wear protective gloves/ protective clothing/ eye protec- 				





Version Revision Date: 7.0 2024/04/06

SDS Number: 734745-00017 Date of last issue: 2023/09/30 Date of first issue: 2016/06/07

tion/ face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification

Important symptoms and out- lines of the emergency as- sumed	:	Dust contact with the eyes can lead to mechanical irritation. Contact with dust can cause mechanical irritation or drying of the skin.
		May form explosive dust-air mixture during processing, han- dling or other means.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture

: Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Starch	9005-25-8	>= 10 - < 20	8-98
(S)-1-[N-[1-(Ethoxycarbonyl)-3- phenylpropyl]-L-alanyl]-L-proline maleate	76095-16-4	>= 1 - < 10	

4. FIRST AID MEASURES

General advice	 In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.
If inhaled	: If inhaled, remove to fresh air. Get medical attention.
In case of skin contact	 In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.
In case of eye contact	: If in eyes, rinse well with water. Get medical attention if irritation develops and persists.
If swallowed	: If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.



Version 7.0	Revision Date: 2024/04/06	-	OS Number: 4745-00017	Date of last issue: 2023/09/30 Date of first issue: 2016/06/07			
	important symptoms effects, both acute and red	:	exposure. Contact with dust the skin.	ge to organs through prolonged or repeated can cause mechanical irritation or drying of			
Prote	ection of first-aiders	:	Dust contact with the eyes can lead to mechanical irritation. First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment				
Notes	s to physician	:	when the potential for exposure exists (see section 8). Treat symptomatically and supportively.				
5. FIREFI	GHTING MEASURES						
Suita	ble extinguishing media	:	Water spray Alcohol-resistant Carbon dioxide (C Dry chemical				
Unsu medi	itable extinguishing a	:	None known.				
	ific hazards during fire-	:	concentrations, a potential dust exp	dust; fine dust dispersed in air in sufficient nd in the presence of an ignition source is a losion hazard. oustion products may be a hazard to health.			
Haza ucts	rdous combustion prod-	:	Carbon oxides Metal oxides				
Spec ods	ific extinguishing meth-	:	cumstances and tuse water spray to	measures that are appropriate to local cir- he surrounding environment. o cool unopened containers. ged containers from fire area if it is safe to do			
	ial protective equipment efighters	:		e, wear self-contained breathing apparatus. rective equipment.			
6. ACCID	ENTAL RELEASE MEA	SUF	RES				
tive e	onal precautions, protec- equipment and emer- y procedures	:	Follow safe hand	ective equipment. ing advice (see section 7) and personal pro- recommendations (see section 8).			
Envir	onmental precautions	:	Retain and dispos	akage or spillage if safe to do so. se of contaminated wash water. should be advised if significant spillages			
	ods and materials for ainment and cleaning up	:	tainer for disposa	dust in the air (i.e., clearing dust surfaces			



Version 7.0	Revision Date: 2024/04/06	SDS Number: 734745-00017	Date of last issue: 2023/09/30 Date of first issue: 2016/06/07
		es, as these ma leased into the Local or nationa posal of this ma employed in the mine which reg Sections 13 an	should not be allowed to accumulate on surfac- ay form an explosive mixture if they are re- atmosphere in sufficient concentration. al regulations may apply to releases and dis- aterial, as well as those materials and items e cleanup of releases. You will need to deter- ulations are applicable. d 15 of this SDS provide information regarding national requirements.
7. HANDL	ING AND STORAGE		
Hand	lling		
Tech	nical measures	causing an exp Provide adequa	 may accumulate and ignite suspended dust losion. ate precautions, such as electrical grounding r inert atmospheres.
Loca	I/Total ventilation		tilation is unavailable, use with local exhaust
	ce on safe handling	: Do not get on s Do not breathe Do not swallow Avoid contact v Wash skin thor Handle in acco practice, based sessment Keep container Keep container Keep away fror Take precautio Do not eat, drin Take care to pr environment.	dust. with eyes. oughly after handling. rdance with good industrial hygiene and safety on the results of the workplace exposure as- tightly closed. generation and accumulation. closed when not in use. n heat and sources of ignition. nary measures against static discharges. k or smoke when using this product. event spills, waste and minimize release to the
	dance of contact ene measures	flushing system place. When using do Wash contamir The effective of engineering con appropriate deg	chemical is likely during typical use, provide eye as and safety showers close to the working not eat, drink or smoke. hated clothing before re-use. peration of a facility should include review of ntrols, proper personal protective equipment, gowning and decontamination procedures, ne monitoring, medical surveillance and the
Stora	age		
Conc	litions for safe storage	: Keep in proper Store locked up Keep tightly clo	



Enalapril Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
7.0	2024/04/06	734745-00017	Date of first issue: 2016/06/07
Materia	als to avoid		ance with the particular national regulations. h the following product types: g agents

Packaging material

: Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Reference concentration / Permissible con- centration	Basis
Starch	9005-25-8	TWA	10 mg/m3	ACGIH
(S)-1-[N-[1-(Ethoxycarbonyl)-3- phenylpropyl]-L-alanyl]-L- proline maleate	76095-16-4	TWA	50 μg/m3 (OEB 3)	Internal
		Wipe limit	500 µg/100 cm ²	Internal

Engineering measures : All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices). Minimize open handling.

Personal protective equipment

Respiratory protection		If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection.
Filter type Hand protection	:	Particulates type
Material	:	Chemical-resistant gloves
Remarks Eye protection	:	Consider double gloving. Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Skin and body protection	:	Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, dis- posable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially



Enalapril Formulation

Version	Revision Date: 2024/04/06	SDS Number:	Date of last issue: 2023/09/30
7.0		734745-00017	Date of first issue: 2016/06/07

contaminated clothing.

9. PHYSICAL AND CHEMICAL P	ROP	ERTIES
Physical state	:	powder
Colour	:	white
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Boiling point, initial boiling point and boiling range	:	No data available
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, han- dling or other means.
Flammability (liquids)	:	No data available
Lower explosion limit and upp Upper explosion limit / Up- per flammability limit		xplosion limit / flammability limit No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	Not applicable
Decomposition temperature	:	No data available
рН	:	No data available
Evaporation rate	:	Not applicable
Auto-ignition temperature	:	No data available
Viscosity Viscosity, kinematic	:	Not applicable
Solubility(ies) Water solubility	:	No data available
Partition coefficient: n- octanol/water	:	Not applicable
Vapour pressure	:	Not applicable
Density and / or relative densi Relative density	ity :	No data available



ersion .0	Revision Date: 2024/04/06		S Number: 4745-00017	Date of last issue: 2023/09/30 Date of first issue: 2016/06/07
De	ensity	:	No data availab	le
Relat	ive vapour density	:	Not applicable	
Explo	osive properties	:	Not explosive	
Oxidi	zing properties	:	The substance of	or mixture is not classified as oxidizing.
	cle characteristics article size	:	No data availab	le
0. STAB	ILITY AND REACTIVITY	,		
	tivity nical stability ibility of hazardous reac-	:	Stable under no May form explose dling or other m	sive dust-air mixture during processing, han
Cond	litions to avoid	:	Heat, flames an	
Haza	Incompatible materials Hazardous decomposition products		Avoid dust form Oxidizing agent No hazardous d	
1. TOXIC	COLOGICAL INFORMAT		l	
Inforr expos	nation on likely routes of sure	:	Inhalation Skin contact Ingestion Eye contact	
	e toxicity lassified based on availa	ble	information.	
Prod Acute	<u>uct:</u> e oral toxicity	:	Acute toxicity est Method: Calculat	timate: > 2,000 mg/kg tion method
Com	ponents:			
Starc	ch:			
Acute	Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg		000 mg/kg	
Acute	e dermal toxicity	:	LD50 (Rabbit): >	2,000 mg/kg
(S)-1	-[N-[1-(Ethoxycarbonyl))-3-p	henylpropyl]-L-a	alanyl]-L-proline maleate:
Acute	e oral toxicity	:	LD50 (Rat): 2,00	0 - 3,500 mg/kg



sion	Revision Date: 2024/04/06	-	S Number: 4745-00017	Date of last issue: 2023/09/30 Date of first issue: 2016/06/07
II			LDLo (Rat): 1,77	75 ma/ka
				2,000 - 3,500 mg/kg
			LDLo (Mouse):	
Aquita	tovicity (other routed of			
	toxicity (other routes of istration)	•	Application Rou	
			LD50 (Mouse): 7 Application Rout	
			LD50 (Dog): > 1	00 mg/kg
			LDLo (Dog): 200) mg/kg
II Skin (corrosion/irritation			
-	assified based on availa	able	information.	
Comp	oonents:			
(0) 4				
(5)-1-	[N-[1-(Etnoxycarbonyi))-3-p	ohenylpropyl]-L-	alanyl]-L-proline maleate:
Speci	es)-3-µ ∶	Rabbit	
Speci	es)-3-p : :		
Specie Resul	es		Rabbit No skin irritation	
Specie Resul	es t	itatio	Rabbit No skin irritation on	
Specie Result Serio Not cl	es t us eye damage/eye irri	itatio	Rabbit No skin irritation on	
Specie Result Serio Not cl	es t us eye damage/eye irri assified based on availa ponents:	itatio	Rabbit No skin irritation on	
Specie Result Serio Not cl <u>Comp</u> Starc	es t us eye damage/eye irri assified based on availa <u>ponents:</u> h: es	itatio	Rabbit No skin irritation on information. Rabbit	
Specie Result Serio Not cl <u>Comp</u> Starc	es t us eye damage/eye irri assified based on availa <u>ponents:</u> h: es	itatio	Rabbit No skin irritation on information.	
Specie Result Serio Not cl Comp Starc Specie Result	es t us eye damage/eye irri assified based on availa <u>ponents:</u> h: es t	itatio	Rabbit No skin irritation on information. Rabbit No eye irritation	
Specie Result Serio Not cl Comp Starc Specie Result (S)-1-	es t us eye damage/eye irri assified based on availa <u>ponents:</u> h: es t [N-[1-(Ethoxycarbonyl) es	itatio	Rabbit No skin irritation on information. Rabbit No eye irritation ohenylpropyl]-L- Rabbit	
Specie Result Serio Not cl Comp Starc Specie Result (S)-1- Specie	es t us eye damage/eye irri assified based on availa <u>ponents:</u> h: es t [N-[1-(Ethoxycarbonyl) es	itatio	Rabbit No skin irritation on information. Rabbit No eye irritation	
Specie Result Not cl Comp Starc Specie Result (S)-1- Specie Result	es t us eye damage/eye irri assified based on availa <u>ponents:</u> h: es t [N-[1-(Ethoxycarbonyl) es	itatio able)-3-r	Rabbit No skin irritation on information. Rabbit No eye irritation ohenylpropyl]-L- Rabbit Severe irritation	
Specie Result Serio Not cl Comp Starc Specie Result (S)-1- Specie Result Result	es t us eye damage/eye irri assified based on availa <u>ponents:</u> h: es t [N-[1-(Ethoxycarbonyl) es t	itatio	Rabbit No skin irritation on information. Rabbit No eye irritation ohenylpropyl]-L- Rabbit Severe irritation n	
Specie Result Serio Not cl Comp Starc Specie Result (S)-1- Specie Result Result Result Skin s Not cl	es t us eye damage/eye irri assified based on availa <u>ponents:</u> h: es t [N-[1-(Ethoxycarbonyl) es t t iratory or skin sensitis sensitisation	itatio	Rabbit No skin irritation on information. Rabbit No eye irritation ohenylpropyl]-L- Rabbit Severe irritation n	
Specie Result Serio Not cl Comp Starc Specie Result (S)-1- Specie Result Result Respie Skin s Not cl Respie	es t us eye damage/eye irri assified based on availa <u>conents:</u> h: es t [N-[1-(Ethoxycarbonyl) es t iratory or skin sensitis sensitisation assified based on availa	itatio able	Rabbit No skin irritation on information. Rabbit No eye irritation ohenylpropyl]-L- Rabbit Severe irritation n	
Specie Result Serio Not cl Comp Starc Specie Result (S)-1- Specie Result Result Result Skin s Not cl Respi Not cl	es t us eye damage/eye irri assified based on availa <u>ponents:</u> h: es t [N-[1-(Ethoxycarbonyl) es t iratory or skin sensitis sensitisation assified based on availa iratory sensitisation	itatio able	Rabbit No skin irritation on information. Rabbit No eye irritation ohenylpropyl]-L- Rabbit Severe irritation n	
Specie Result Serio Not cl Comp Starc Specie Result (S)-1- Specie Result Result Result Skin s Not cl Respi Not cl	es t us eye damage/eye irri assified based on availa <u>conents:</u> h: es t [N-[1-(Ethoxycarbonyl) es t iratory or skin sensitist sensitisation assified based on availa iratory sensitisation assified based on availa ponents:	itatio able	Rabbit No skin irritation on information. Rabbit No eye irritation ohenylpropyl]-L- Rabbit Severe irritation n	



Date of last issue: 2023/09/30

Enalapril Formulation

Revision Date:

Version

		734745-00017	Date of first issue: 2016/06/07
Exposi	ure routes	: Skin contact	
Specie	S	: Guinea pig	
Result		: negative	
]-L-alanyl]-L-proline maleate:
Test Ty	/pe ure routes	: Maximisatior : Skin contact	
Specie		: Guinea pig	
Result	-	: Not a skin se	ensitizer.
Germ	cell mutagenicity		
	ssified based on av	ailable information.	
<u>Compo</u> Starch	<u>onents:</u> :		
	oxicity in vitro	· Test Tune· R	acterial reverse mutation assay (AMES)
Centre		Result: nega	
(S)-1-[I	N-[1-(Ethoxycarbo	ıyl)-3-phenylpropyl]-L-alanyl]-L-proline maleate:
Genoto	oxicity in vitro	: Test Type: B Result: nega	acterial reverse mutation assay (AMES) tive
		Test Type: Ir malian cells	n vitro sister chromatid exchange assay in m
		Result: nega	tive
		Test Type: A Result: nega	Ikaline elution assay tive
Genoto	oxicity in vivo		Ammalian erythrocyte micronucleus test (in
		cytogenetic a Species: Mo	
			Route: Ingestion
			Autagenicity (in vivo mammalian bone-marro est, chromosomal analysis)
		Species: Mo	
		Application F	Route: Ingestion
		Result: nega	tive
	ogenicity		
_	ssified based on av	ailable information.	
	onents:		
(S)-1-[I Specie		ıyl)-3-phenylpropyl : Rat]-L-alanyl]-L-proline maleate:
	ation Route	: Ingestion	
		9 /	16

SDS Number:



Enalapril Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
7.0	2024/04/06	734745-00017	Date of first issue: 2016/06/07

Exposure time NOAEL Result	:	106 weeks 90 mg/kg body weight negative
Species Application Route Exposure time NOAEL Result	:	Mouse Ingestion 94 weeks 90 - 180 mg/kg body weight negative

Reproductive toxicity

May damage the unborn child.

Components:

(S)-1-[N-[1-(Ethoxycarbonyl))-3-	phenylpropyl]-L-alanyl]-L-proline maleate:
Effects on fertility	:	Test Type: Fertility Species: Rat, male and female Application Route: Ingestion Fertility: NOAEL: 90 mg/kg body weight Result: No effects on fertility
Effects on foetal develop- ment	:	Species: Rat Application Route: Ingestion Developmental Toxicity: NOAEL: 200 mg/kg body weight Result: No effects on foetal development
		Species: Rat Application Route: Ingestion Developmental Toxicity: LOAEL: 1,200 mg/kg body weight Result: Fetotoxicity
		Species: Rat Application Route: Ingestion Developmental Toxicity: LOAEL: 30 mg/kg body weight Result: Effects on postnatal development, Effects on newborn, No teratogenic effects
		Species: Rabbit Application Route: Ingestion General Toxicity Maternal: LOAEL: 1 mg/kg body weight Developmental Toxicity: LOAEL: 1 mg/kg body weight Result: Fetotoxicity, Maternal toxicity observed., No teratogen- ic effects
Reproductive toxicity - As- sessment	:	Positive evidence of adverse effects on development from human epidemiological studies.

STOT - single exposure

Not classified based on available information.



Enalapril Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
7.0	2024/04/06	734745-00017	Date of first issue: 2016/06/07

STOT - repeated exposure

May cause damage to organs (Kidney, Cardio-vascular system) through prolonged or repeated exposure.

Components:

(S)-1-[N-[1-(Ethoxycarbonyl)-3-phenylpropyl]-L-alanyl]-L-proline maleate:

Target Organs Assessment	Kidney, Cardio-vascular system Causes damage to organs through prolonged or repeated exposure.
	exposure.

Repeated dose toxicity

Components:

Starch:

Species NOAEL Application Route Exposure time	:	Rat >= 2,000 mg/kg Skin contact 28 Days
Method		OECD Test Guideline 410
Method	•	OECD Test Guideline 410

(S)-1-[N-[1-(Ethoxycarbonyl)-3-phenylpropyl]-L-alanyl]-L-proline maleate:

Species	Dog
NOAEL	15 mg/kg
LOAEL	30 mg/kg
Application Route	Ingestion
Exposure time	: 1 yr
Target Organs	: Kidney
Species	: Rat
NOAEL	: 90 mg/kg
Application Route	: Oral
Exposure time	: 1 yr
Remarks	: No significant adverse effects were reported
Species NOAEL Application Route Exposure time Remarks	 Monkey 30 mg/kg Oral 1 Months No significant adverse effects were reported

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

(S)-1-[N-[1-(Ethoxycarbonyl)-3-phenylpropyl]-L-alanyl]-L-proline maleate: Ingestion : Target Organs: Cardio-vascular system



Enalapril Formulation

Version 7.0	Revision Date: 2024/04/06	SDS Number: 734745-00017	Date of last issue: 2023/09/30 Date of first issue: 2016/06/07	

Symptoms: hypotension, Cough, Dizziness, Headache, Blurred vision, Fatigue, Oedema, Nausea, hyperkalemia, fainting, Weakness, skin rash Remarks: May cause harm to the unborn child.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

(S)-1-[N-[1-(Ethoxycarbonyl)-3-phenylpropyl]-L-alanyl]-L-proline maleate:

Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): > 1,000 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 346 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to microorganisms	:	EC50 (Natural microorganism): > 1,000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

Hazardous to the ozone layer

Not applicable

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods		
Waste from residues	:	Dispose of in accordance with local regulations. Do not dispose of waste into sewer.
Contaminated packaging	:	Empty containers should be taken to an approved waste han- dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.



Enalapril Formulation

Version	Revision Date:
7.0	2024/04/06

SDS Number: 734745-00017

Date of last issue: 2023/09/30 Date of first issue: 2016/06/07

14. TRANSPORT INFORMATION

International Regulations

UNRTDG UN number Proper shipping name Class Subsidiary risk Packing group Labels Environmentally hazardous	Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable no
IATA-DGR UN/ID No. Proper shipping name Class Subsidiary risk Packing group Labels Packing instruction (cargo aircraft) Packing instruction (passen- ger aircraft)	Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable
IMDG-Code UN number Proper shipping name Class Subsidiary risk Packing group Labels EmS Code Marine pollutant	Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations

Refer to section 15 for specific national regulation.

Special precautions for user

Not applicable

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law

Not applicable to dangerous materials / designated flammables.



Enalapril Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
7.0	2024/04/06	734745-00017	Date of first issue: 2016/06/07

Chemical Substance Control Law

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture

Not applicable

Harmful Substances Required Permission for Manufacture

Not applicable

Substances Prevented From Impairment of Health

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

Substances Subject to be Notified Names

Not applicable

Substances Subject to be Indicated Names

Not applicable

Substances Subject to be Indicated Names

Not applicable

Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regula-

tions) Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances Not applicable

Ordinance on Prevention of Lead Poisoning

Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

Ordinance on Prevention of Organic Solvent Poisoning

Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)

Not applicable

Poisonous and Deleterious Substances Control Law

Not applicable



Enalapril Formulation

ersion D	Revision Date: 2024/04/06	SDS Number: 734745-00017	Date of last issue: 2023/09/30 Date of first issue: 2016/06/07
vironr			of Specific Chemical Substances in the E the Management Thereof
-	Pressure Gas Safet	y Act	
	oplicable		
•	sive Control Law		
	oplicable		
	el Safety Law gulated as a danger	ous good	
Aviati	on Law gulated as a danger	-	
Marin	e Pollution and Sea	Disaster Prevention	etc Law
Bulk tr	ransportation	: Not classified a	as noxious liquid substance
Pack t	ransportation	: Not classified a	as marine pollutant
Narco Not ap Specif	plicable	aw Material (Export / I	mport Permission) Export / Import permission)
	Disposal and Pub rial waste	lic Cleansing Law	
The c AICS	omponents of this	product are reported : not determined	in the following inventories:
DSL		: not determined	1
IECSO	2	: not determined	1

Further information

Sources of key data used to :	Internal technical data, data from raw material SDSs, OECD
compile the Safety Data	eChem Portal search results and European Chemicals Agen-
Sheet	cy, http://echa.europa.eu/

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format	:	yyyy/mm/dd
Full text of other abbreviation	ns	
ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)



Enalapril Formulation

Version	Revision Date:
7.0	2024/04/06

SDS Number: 734745-00017 Date of last issue: 2023/09/30 Date of first issue: 2016/06/07

ACGIH / TWA

: 8-hour, time-weighted average

AIIC - Australian Inventory of Industrial Chemicals: ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance: PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

JP / EN