

according to the Hazardous Products Regulations

# **Ramipril Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
3.1	09/30/2023	3517176-00012	Date of first issue: 10/11/2018

#### **SECTION 1. IDENTIFICATION**

Product name	:	Ramipril Formulation
Other means of identification	:	No data available

#### Manufacturer or supplier's details

Company name of supplier	:	Merck & Co., Inc
Address	:	126 E. Lincoln Avenue
		Rahway, New Jersey U.S.A. 07065
Telephone	:	908-740-4000
Emergency telephone	:	1-908-423-6000
E-mail address	:	EHSDATASTEWARD@merck.com

### Recommended use of the chemical and restrictions on use

Recommended use	:	Veterinary product
Restrictions on use	:	Not applicable

#### **SECTION 2. HAZARDS IDENTIFICATION**

GHS classification in accordance with the Hazardous Products Regulations Skin sensitization : Sub-category 1B					
Reproductive toxicity	:	Category 1A			
Specific target organ toxicity - repeated exposure (Oral)	:	Category 2 (Kidney)			
GHS label elements Hazard pictograms	:				
Signal Word	:	Danger			
Hazard Statements	:	H317 May cause an allergic skin reaction. H360D May damage the unborn child. H373 May cause damage to organs (Kidney) through prolonged or repeated exposure if swallowed.			
Precautionary Statements	:	<ul> <li>Prevention:</li> <li>P201 Obtain special instructions before use.</li> <li>P202 Do not handle until all safety precautions have been read and understood.</li> <li>P260 Do not breathe dust.</li> <li>P272 Contaminated work clothing should not be allowed out of the workplace.</li> <li>P280 Wear protective gloves, protective clothing, eye protection and face protection.</li> </ul>			

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#### Response:

P302 + P352 IF ON SKIN: Wash with plenty of water.

P308 + P313 IF exposed or concerned: Get medical attention. P333 + P313 If skin irritation or rash occurs: Get medical atten-

tion.

P362 + P364 Take off contaminated clothing and wash it before reuse.

#### Storage:

P405 Store locked up.

#### Disposal:

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

#### Other hazards

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, handling or other means.

#### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Starch	Sago starch	9005-25-8	>= 30 - < 60 *
Cellulose	No data availa- ble	9004-34-6	>= 30 - < 60 *
Ramipril	No data availa- ble	87333-19-5	>= 10 - < 30 *
Hydrolyzed Vegetable Protein	No data availa- ble	Not Assigned	>= 5 - < 10 *
Natural Pork Flavor	No data availa- ble	Not Assigned	>= 1 - < 5 *
Hydrogenated Vegeta- ble Oil	No data availa- ble	Not Assigned	>= 1 - < 5 *

<sup>\*</sup> Actual concentration or concentration range is withheld as a trade secret

#### SECTION 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.

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		Get medical att				
		Wash clothing				
	an of our contact	Thoroughly clean shoes before reuse.				
IN Ce	se of eye contact		If in eyes, rinse well with water. Get medical attention if irritation develops and persists.			
If swallowed		: If swallowed, D Get medical att	If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.			
Mos	t important symptoms	: May cause an allergic skin reaction.				
	effects, both acute and		May damage the unborn child.			
delayed		May cause dan	May cause damage to organs through prolonged or repeated exposure if swallowed.			
		Contact with du	ist can cause mechanical irritation or drying of			
		Dust contact wi	ith the eyes can lead to mechanical irritation.			
Prote	ection of first-aiders	and use the red	nders should pay attention to self-protection, commended personal protective equipment itial for exposure exists (see section 8).			
Note	s to physician		atically and supportively.			

### SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media		Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical None known.
media	•	
Specific hazards during fire fighting	:	Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.
Hazardous combustion prod- ucts	:	Carbon oxides
Specific extinguishing meth- ods	:	Use extinguishing measures that are appropriate to local cir- cumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for fire-fighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

### SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- tive equipment and emer- gency procedures	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
Environmental precautions	:	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water.

SAFETY DATA SHEET according to the Hazardous Products Regulations



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Methods and materials for containment and cleaning up	Local authorities cannot be contained : Sweep up or vac container for disp Avoid dispersal of with compressed Dust deposits sh surfaces, as thes released into the Local or national disposal of this n employed in the determine which Sections 13 and	cuum up spillage and collect in suitable bosal. of dust in the air (i.e., clearing dust surfaces

### SECTION 7. HANDLING AND STORAGE

Technical measures	<ul> <li>Static electricity may accumulate and ignite suspended dust causing an explosion.</li> <li>Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.</li> </ul>
Local/Total ventilation	If sufficient ventilation is unavailable, use with local exhaust ventilation.
Advice on safe handling	<ul> <li>Do not get on skin or clothing.</li> <li>Do not breathe dust.</li> <li>Do not swallow.</li> <li>Avoid contact with eyes.</li> <li>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment</li> <li>Keep container tightly closed.</li> <li>Minimize dust generation and accumulation.</li> <li>Keep container closed when not in use.</li> <li>Keep away from heat and sources of ignition.</li> <li>Take precautionary measures against static discharges.</li> <li>Take care to prevent spills, waste and minimize release to the</li> </ul>
Conditions for safe storage	environment. Keep in properly labeled containers. Store locked up. Keep tightly closed.
Materials to avoid	<ul> <li>Store in accordance with the particular national regulations.</li> <li>Do not store with the following product types:</li> <li>Strong oxidizing agents</li> <li>Self-reactive substances and mixtures</li> <li>Organic peroxides</li> <li>Explosives</li> <li>Gases</li> </ul>



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#### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Starch	9005-25-8	TWA	10 mg/m <sup>3</sup>	CA AB OEL
		TWA (Total dust)	10 mg/m³	CA BC OEL
		TWA (respir- able dust fraction)	3 mg/m <sup>3</sup>	CA BC OEL
		TWAEV (to- tal dust)	10 mg/m³	CA QC OEL
		TWA	10 mg/m <sup>3</sup>	ACGIH
Cellulose	9004-34-6	TWA	10 mg/m <sup>3</sup>	CA AB OEL
		TWA (Total dust)	10 mg/m³	CA BC OEL
		TWA (respir- able dust fraction)	3 mg/m³	CA BC OEL
		TWAEV (to- tal dust)	10 mg/m³	CA QC OEL
		TWA	10 mg/m <sup>3</sup>	ACGIH
Ramipril	87333-19-5	TWA	3 µg/m3 (OEB 4)	Internal
		Wipe limit	30 µg/100cm2	Internal

Engineering measures :	Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., vacuum conveying from a closed system, packout head with inflatable seal from stationary container, ventilated enclosure, etc.). All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Essentially no open handling permitted. Use closed processing systems or containment technologies.
Personal protective equipment	t
Respiratory protection   :     Filter type   :	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Particulates type
Hand protection	
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

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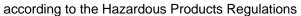


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Skin a	and body protection	aerosols. : Work uniform o Additional body task being perfo	ect contact to the face with dusts, mists, or r laboratory coat. garments should be used based upon the prmed (e.g., sleevelets, apron, gauntlets, s) to avoid exposed skin surfaces.
Hygie	ne measures	Use appropriate contaminated c : If exposure to c	e degowning techniques to remove potentially
		working place. When using do Contaminated v	not eat, drink or smoke. vork clothing should not be allowed out of the
		The effective op	ated clothing before re-use. peration of a facility should include review of ntrols, proper personal protective equipment,
		appropriate deg	jowning and decontamination procedures, ne monitoring, medical surveillance and the

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder
Color	:	No data available
Odor	:	No data available
Odor Threshold	:	No data available
рН	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	Not applicable
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	Not applicable





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	Relative	e vapor density	:	Not applicable	
	Relative	edensity	:	No data available	
	Density		:	No data available	
	Solubilit Wate	ty(ies) er solubility	:	No data available	
		n coefficient: n-	:	Not applicable	
	octanol/ Autoign	water ition temperature	:	No data available	
	Decomp	position temperature	:	No data available	
	Viscosit Visco	y osity, kinematic	:	Not applicable	
	Explosiv	ve properties	:	Not explosive	
	Ovidizin	ig properties		The substance of	mixture is not classified as oxidizing.
			•		, and the second s
	Molecul	ar weight	:	No data available	
	Particle	size	:	No data available	

#### SECTION 10. STABILITY AND REACTIVITY

Reactivity Chemical stability Possibility of hazardous reac- tions	<ul> <li>Not classified as a reactivity hazard.</li> <li>Stable under normal conditions.</li> <li>May form explosive dust-air mixture during processing, handling or other means.</li> <li>Can react with strong oxidizing agents.</li> </ul>
Conditions to avoid Incompatible materials Hazardous decomposition products	<ul> <li>Heat, flames and sparks. Avoid dust formation.</li> <li>Oxidizing agents</li> <li>No hazardous decomposition products are known.</li> </ul>

### SECTION 11. TOXICOLOGICAL INFORMATION

#### Information on likely routes of exposure

Inhalation Skin contact Ingestion Eye contact

#### Acute toxicity

Not classified based on available information.

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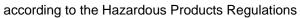


Someonents:         Starch:         Acute oral toxicity       :       LD50 (Rat): > 5,000 mg/kg         Acute dermal toxicity       :       LD50 (Rat): > 2,000 mg/kg         Celluose:       .       .         Acute oral toxicity       :       LD50 (Rat): > 5,000 mg/kg         Acute inhalation toxicity       :       LC50 (Rat): > 5,8 mg/t         Acute inhalation toxicity       :       LC50 (Rat): > 5,000 mg/kg         Acute dermal toxicity       :       LD50 (Rat): > 10,000 mg/kg         Acute oral toxicity       :       LD50 (Dog): > 250 mg/kg         Acute toxicity (other routes of administration)       :       LD50 (Dog): > 250 mg/kg         Application Route: Intravenous       .       LD50 (Rat): 600 mg/kg         Application Route: Intravenous       .       .         Stin corrosion/irritation       .       .         Not classified based on available information.       .       .         Schoos eye damage/eye irritation       .       .         Not classified based on available information.       .       .         Schoos eye damage/eye irritation       .       .         Result       :       No eye irritation         More classified based on available information.       .	ersion 1	Revision Date: 09/30/2023		0S Number: 17176-00012	Date of last issue: 04/04/2023 Date of first issue: 10/11/2018
Acute oral toxicity $:$ LD50 (Rat): > 5,000 mg/kgAcute dermal toxicity $:$ LD50 (Rabbit): > 2,000 mg/kgAcute oral toxicity $:$ LD50 (Rat): > 5,000 mg/kgAcute inhalation toxicity $:$ LD50 (Rat): > 5,8 mg/l Exposure time: 4 h Test atmosphere: dust/mistAcute dermal toxicity $:$ LD50 (Rat): > 5,200 mg/kgAcute dermal toxicity $:$ LD50 (Rat): > 2,000 mg/kgAcute oral toxicity $:$ LD50 (Rat): > 10,000 mg/kgAcute oral toxicity $:$ LD50 (Rat): > 10,000 mg/kgAcute toxicity (other routes of administration) $:$ LD50 (Dog): > 250 mg/kg Application Route: Intravenous LD50 (Rat): 600 mg/kg Application Route: IntravenousSkin corrosion/irritation $:$ Not classified based on available information.Serious eye damage/eye irritation Not classified based on available information. $:$ Sepiratory or skin sensitization May cause an allergic skin reaction. $:$ Respiratory or skin sensitization May cause an allergic skin reaction. $:$ May cause an allergic skin reaction. $:$ Respiratory sensitization May cause an allergic skin reaction. $:$ Not classified based on available information. $:$ Components: Starch: Test Type $:$ Maximization Test $:$ Not classified based on available information.Components: 	<u>Comp</u>	oonents:			
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Cellulose:         Acute oral toxicity       ::       LD50 (Rat): > 5,000 mg/kg         Acute inhalation toxicity       ::       LC50 (Rat): > 5.8 mg/l         Exposure time: 4 h       Test atmosphere: dust/mist         Acute dermal toxicity       ::       LD50 (Rat): > 2,000 mg/kg         Acute oral toxicity       ::       LD50 (Rat): > 10,000 mg/kg         Acute oral toxicity       ::       LD50 (Dog): > 1,000 mg/kg         Acute toxicity (other routes of       ::       LD50 (Dog): > 250 mg/kg         Acute toxicity (other routes of       ::       LD50 (Dog): > 250 mg/kg         Administration       :       LD50 (Dog): > 250 mg/kg         Application Route: Intravenous       LD50 (Rat): 600 mg/kg         Mot classified based on available information.       Emplitient information.         Components:       :       No eye irritation         May cause an allergic s	Acute	oral toxicity	:	LD50 (Rat): > 5,00	00 mg/kg
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Respiratory sensitization         Not classified based on available information.         Components:         Starch:         Test Type       : Maximization Test			actio	on.	
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Starch: Test Type : Maximization Test					
Test Type : Maximization Test					
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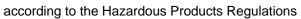
according to the Hazardous Products Regulations

rsion	Revision Date: 09/30/2023		OS Number: 17176-00012	Date of last issue: 04/04/2023 Date of first issue: 10/11/2018
Specie Resul		:	Guinea pig negative	
	<b>al Pork Flavor:</b> ssment	:	The product is	a skin sensitizer, sub-category 1B.
	cell mutagenicity assified based on ava	ailable	information.	
Comp	oonents:			
Starc	h:			
Genot	toxicity in vitro	:	Test Type: Bac Result: negative	terial reverse mutation assay (AMES) e
Cellul	lose:			
Genot	toxicity in vitro	:	Test Type: Bac Result: negative	terial reverse mutation assay (AMES) e
			Test Type: In vi Result: negative	tro mammalian cell gene mutation test e
Genot	toxicity in vivo	:	Test Type: Mar cytogenetic ass Species: Mouse Application Rou Result: negative	e ite: Ingestion
Ramij	pril:			
Genot	toxicity in vitro	:	Test Type: Bac Result: negative	terial reverse mutation assay (AMES) e
			Test Type: uns Result: negative	cheduled DNA synthesis assay e
				tro mammalian cell gene mutation test hinese hamster ovary cells e
Genot	toxicity in vivo	:	Test Type: Mice Species: mice Result: negative	
	<b>nogenicity</b> assified based on ava	ailable	information.	
	oonents:			
Cellul				
Specie		:	Rat Ingestion	



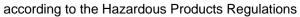


Vers 3.1	-	Revision Date: 09/30/2023	-	S Number: 17176-00012	Date of last issue: 04/04/2023 Date of first issue: 10/11/2018
	Exposure Result	e time	:	72 weeks negative	
	Exposure NOAEL Result Species	on Route e time on Route		Rat Oral 24 month(s) 500 mg/kg body w negative Rat Oral 18 month(s) 1,000 mg/kg body negative	
	Reprodu	uctive toxicity	•	negative	
	<u>Compor</u>	0	•		
	Cellulos Effects o	<b>e:</b> n fertility	:	Test Type: One-ge Species: Rat Application Route: Result: negative	eneration reproduction toxicity study
	Effects o	n fetal development	:	Test Type: Fertility Species: Rat Application Route: Result: negative	/early embryonic development
	Ramipri	I:			
	Effects o	n fertility	:	Test Type: Fertility Species: Rat Application Route: Fertility: NOAEL: 5 Result: No advers	Oral 500 mg/kg body weight
	Effects o	n fetal development	:		
					Oral xicity: LOAEL: 50 mg/kg body weight ons were observed.





rsion	Revision Date: 09/30/2023	SDS Number: 3517176-00012	Date of last issue: 04/04/2023 Date of first issue: 10/11/2018
			bbit
			nkey
			nkey
Repro sessm	oductive toxicity - As- nent	: May damage	the unborn child.
sessm STOT			the unborn child.
sessm STOT Not cl	nent -single exposure assified based on ava		the unborn child.
sessm STOT Not cl STOT	nent -single exposure assified based on ava -repeated exposure	ilable information.	the unborn child. prolonged or repeated exposure if swallowed.
sessm STOT Not cl STOT May c	nent -single exposure assified based on ava -repeated exposure	ilable information.	
sessm STOT Not cl STOT May c <u>Comp</u>	nent -single exposure assified based on avain -repeated exposure cause damage to organ conents:	ilable information.	
sessm STOT Not cl STOT May c <u>Comp</u> Ramij	nent -single exposure assified based on avain -repeated exposure cause damage to organ conents: pril:	ilable information.	
sessm STOT Not cl STOT May c Comp Ramij Route Targe	nent -single exposure assified based on avain -repeated exposure cause damage to organ conents:	ilable information. ns (Kidney) through : Oral : Kidney	
sessm STOT Not cl STOT May c Comp Rami Route Targe Asses	nent -single exposure assified based on avai -repeated exposure cause damage to organ <u>conents:</u> pril: es of exposure of organs	ilable information. ns (Kidney) through : Oral : Kidney : May cause d	prolonged or repeated exposure if swallowed.
sessm STOT Not cl STOT May c Comp Ramin Route Targe Asses Repea	nent -single exposure assified based on avai -repeated exposure cause damage to organ conents: pril: es of exposure of Organs ssment	ilable information. ns (Kidney) through : Oral : Kidney : May cause d	prolonged or repeated exposure if swallowed.
sessm STOT Not cl STOT May c Comp Ramin Route Targe Asses Repea	nent -single exposure assified based on avai -repeated exposure cause damage to organ conents: pril: es of exposure of Organs ssment ated dose toxicity conents:	ilable information. ns (Kidney) through : Oral : Kidney : May cause d	prolonged or repeated exposure if swallowed.
sessm STOT Not cl STOT May c Comp Ramin Route Targe Asses Repea Comp Starc Specie	nent -single exposure assified based on avail -repeated exposure cause damage to organ conents: pril: es of exposure of exposure ssment ated dose toxicity conents: h: es	ilable information. ns (Kidney) through : Oral : Kidney : May cause d exposure. : Rat	prolonged or repeated exposure if swallowed. amage to organs through prolonged or repeated
sessm STOT Not cl STOT May c Comp Ramin Route Targe Asses Repea Starc Specie NOAE	nent -single exposure assified based on avail -repeated exposure cause damage to organ conents: pril: es of exposure of Organs ated dose toxicity conents: h: es L	ilable information. ns (Kidney) through : Oral : Kidney : May cause d exposure. : Rat : >= 2,000 mg.	prolonged or repeated exposure if swallowed. amage to organs through prolonged or repeated
sessin STOT Not cl STOT May c Comp Ramin Route Targe Asses Repea Starc Specie NOAE Applic	nent -single exposure assified based on avail -repeated exposure cause damage to organ conents: pril: es of exposure of Organs ated dose toxicity conents: h: es EL cation Route	ilable information. ns (Kidney) through : Oral : Kidney : May cause d exposure. : Rat	prolonged or repeated exposure if swallowed. amage to organs through prolonged or repeated
sessin STOT Not cl STOT May c Comp Ramin Route Targe Asses Repea Starc Specie NOAE Applic	nent -single exposure assified based on avail -repeated exposure cause damage to organ conents: pril: es of exposure of Organs ated dose toxicity conents: h: es EL cation Route sure time	ilable information. ns (Kidney) through : Oral : Kidney : May cause d exposure. : Rat : >= 2,000 mg. : Skin contact : 28 Days	prolonged or repeated exposure if swallowed. amage to organs through prolonged or repeated
sessin STOT Not cl STOT May c Comp Rami Route Targe Asses Repea Starc Specie NOAE Applic Expos	nent -single exposure assified based on availation -repeated exposure cause damage to organ conents: pril: es of exposure of Organs ated dose toxicity conents: h: es EL cation Route sure time od	ilable information. ns (Kidney) through : Oral : Kidney : May cause d exposure. : Rat : >= 2,000 mg. : Skin contact : 28 Days	prolonged or repeated exposure if swallowed. amage to organs through prolonged or repeated
sessin STOT Not cl STOT May c Comp Ramij Route Targe Asses Repea Starc Specie NOAE Applic Expos Metho	nent -single exposure assified based on avail -repeated exposure cause damage to organ conents: pril: es of exposure of exposure of Organs ssment ated dose toxicity conents: h: es EL cation Route sure time od lose: es	ilable information. ns (Kidney) through : Oral : Kidney : May cause d exposure. : Rat : >= 2,000 mg. : Skin contact : 28 Days	prolonged or repeated exposure if swallowed. amage to organs through prolonged or repeated /kg Guideline 410





# **Ramipril Formulation**

ersion 1	Revision Date: 09/30/2023	SDS Number: 3517176-00012	Date of last issue: 04/04/2023 Date of first issue: 10/11/2018
	cation Route sure time	: Ingestion : 90 Days	
Rami	pril:		
Speci	es	: Mouse	
LÒAE		: 100 mg/kg	
	cation Route	: Oral	
Targe Symp	et Organs toms	: Blood, Kidney : kidney effects	
Speci		: Rat	
NOAE		: 2 mg/kg	
Applic	cation Route	: Oral	
Speci		: Dog	
NOAE		: 2.5 mg/kg	
LOAE		: 250 mg/kg	
	cation Route	: Oral	
Symp	et Organs	: Blood, Kidney : kidney effects	
Speci		: Monkey	
NOAE		: 8 mg/kg	
LOAE		: 250 mg/kg	
	cation Route	: Oral	
Symp	et Organs	: Blood, Kidney : kidney effects	
Oymp	lonis	. Kidney enects	
•	ation toxicity assified based on ava	ilable information.	
Expe	rience with human e	xposure	
<u>Com</u>	oonents:		
Rami	pril:		
Inges	tion		llergic reactions, Kidney disorders, liver function , Cough, Dizziness, Nausea, Headache, Vomit-
ECTION	12. ECOLOGICAL IN	IFORMATION	
Facto			
	oxicity		
	<u>oonents:</u>		
Cellu			
Toxic	ity to fish	Exposure time	s latipes (Japanese medaka)): > 100 mg/l e: 48 h sed on data from similar materials
		Remarks. Das	

### Ramipril:

according to the Hazardous Products Regulations



# **Ramipril Formulation**

	rision Date: 30/2023	-	S Number: 17176-00012	Date of last issue: 04/04/2023 Date of first issue: 10/11/2018	
Toxicity to fish		:	LC50 (Brachydanio rerio (zebrafish)): > 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203		
Toxicity to daphnia and other aquatic invertebrates		:	EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h Method: OECD Test Guideline 202		
Toxicity to algae/aquatic plants		:	EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l Exposure time: 72 h Method: OECD Test Guideline 201		
Hydrolyzed	Vegetable Prote	in:			
Ecotoxicolo Acute aquat	ogy Assessment ic toxicity	:	Toxic effects canr	not be excluded	
Chronic aqu	Chronic aquatic toxicity		Toxic effects cannot be excluded		
Natural Por	k Flavor:				
	ogy Assessment				
Acute aquat	·	:	Toxic effects canr		
Chronic aqu	atic toxicity	:	Toxic effects cannot be excluded		
Hydrogena	ted Vegetable Oi	l:			
Ecotoxicolo Acute aquat	bgy Assessment ic toxicity	:	Toxic effects canr	not be excluded	
Chronic aqu	atic toxicity	:	Toxic effects cann	not be excluded	
Persistence	e and degradabili	ity			
Componen	ts:				
Cellulose:					
Biodegradal	bility	:	Result: Readily bi	odegradable.	
Ramipril: Biodegradability		:	Result: Not readily biodegradable. Biodegradation: 20 - 50 % Exposure time: 28 d Method: OECD Test Guideline 301A		

No data available

according to the Hazardous Products Regulations



### **Ramipril Formulation**

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	<b>lity in soil</b> ata available					
	Other adverse effects No data available					
SECTION 13. DISPOSAL CONSIDERATIONS						
Dispo	osal methods					
Wast	e from residues	•	: Do not dispose of waste into sewer. Dispose of in accordance with local regulations.			
Conta	aminated packaging	: Empty cont handling sit	<ul> <li>Empty containers should be taken to an approved waste handling site for recycling or disposal.</li> <li>If not otherwise specified: Dispose of as unused product.</li> </ul>			
SECTION	SECTION 14. TRANSPORT INFORMATION					
Interi	national Regulations					

#### -----

**UNRTDG** Not regulated as a dangerous good

#### IATA-DGR

Not regulated as a dangerous good

#### IMDG-Code

Not regulated as a dangerous good

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

Not applicable for product as supplied.

### Domestic regulation

**TDG** Not regulated as a dangerous good

#### Special precautions for user

Not applicable

#### **SECTION 15. REGULATORY INFORMATION**

The i	ngredients of this prod	uct	are reported in the following
AICS	,	:	not determined
DSL		:	not determined
IECS	С	:	not determined

### **SECTION 16. OTHER INFORMATION**

# Full text of other abbreviations ACGIH : USA. ACGIH Threshold Limit Values (TLV)

inventories:

according to the Hazardous Products Regulations



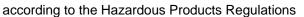
### **Ramipril Formulation**

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CA A	B OEL	: Canada. Alb 2: OEL)	erta, Occupational Health and Safety Code (table		
CA BC OEL		: Canada. Brit	: Canada. British Columbia OEL		
CA QC OEL		ty, Schedule	: Québec. Regulation respecting occupational health and safe- ty, Schedule 1, Part 1: Permissible exposure values for air- borne contaminants		
ACGIH / TWA			: 8-hour, time-weighted average		
CA AB OEL / TWA			8-hour Occupational exposure limit		
	C OEL / TWA		weighted average		
CA QC OEL / TWAEV		: Time-weight	ed average exposure value		

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

Sources of key data used to compile the Material Safety Data Sheet	:	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen- cy, http://echa.europa.eu/
Revision Date Date format	:	09/30/2023 mm/dd/yyyy

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





### Ramipril Formulation

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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.

CA / Z8