



SAFETY DATA SHEET

In compliance with Regulation (CE) n. 1907/2006 and (UE)n. 453/2010 (Annex I)

Issuing Date 04-Jan-2011

Revision Date 08-Mar-2011

Revision Number 3

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

1.1. Product identifier

Product Name	LISINOPRIL
Chemical Name:	L-Proline, 1-(N2-(1-carboxy-3-phenylpropyl)-L-lysyl)-, (S)-, dihydrate
Synonyms	1-(N2((S)-1-Carboxy-3-phenylpropyl)lysyl)proline dihydrate; Lisinopril dihydrate, Dapril, Lisocard, Lisodura, Lisoril, Novatec, Prinivil Vivatec, Zestril
Formula	C ₂₁ H ₃₁ N ₃ O ₅ · 2H ₂ O
CAS	83915-83-7
EINECS	Not available
Index Number	Not available
Reach Registration Number	Not available

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified Use	Active Pharmaceutical Ingredient
Uses advised against	No information available

1.3. Details of the supplier of the safety data sheet

Manufacturer, Supplier	TAPI Puerto Rico Inc. Road #3 KM, 143.0 P.O.Box 10010 Guyama, PR 00784, USA Tel: 787-864-4545
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For further information, please contact

E-mail Address	Not available (Puerto Rico)
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1.4. Emergency telephone number

Emergency Telephone Number	CHEMTREC, US: 1-800-424-9300, International: 1-703-527-3887
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SECTION 2. Hazards identification

2.1. Classification of the substance or mixture REGULATION (EC) No 1272/2008

Chemical Name	CLP/GHS classification
L-Proline, 1-(N2-(1-carboxy-3-phenylpropyl)-L-lysyl)-, (S)-, dihydrate	Repr. 2 H361d

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

Chemical Name	EU Classification
L-Proline, 1-(N2-(1-carboxy-3-phenylpropyl)-L-lysyl)-, (S)-, dihydrate	Repr. Cat. 3; R63

Full text of phrases reported in section 16

2.2. Label Elements

Signal Word

Warning



Hazard Statements

H361d - Suspected of damaging the unborn child

Precautionary Statements

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

2.3. Other hazards

Not available

SECTION 3. Composition/information on ingredients

3.1. Substances

Chemical Name	EC No.	REACH Reg. No.	CAS-No	Weight %
L-Proline, 1-(N2-(1-carboxy-3-phenylpropyl)-L-lysyl)-, (S)-, dihydrate	-	Not available	83915-83-7	100

3.2. Mixtures

N.A.

SECTION 4. First aid measures

4.1. Description of first-aid measures

Eye Contact	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician
Skin Contact	Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes
Ingestion	Get medical attention. Clean mouth with water, only if the person is in conscious.
Inhalation	Remove from exposure, lie down. If breathing is difficult, give oxygen. If not breathing, give artificial respiration.

4.2. Most important symptoms and effects, both acute and delayed

Most Important Symptoms/Effects

Irritation:	No information available.
Corrosivity:	No information available
Sensitization	No information available
Eyes:	N/A
Skin:	May cause: Skin rash.
Inhalation:	May cause: Cough, Infection, Nasal congestion, Influenza.
Ingestion:	May cause: Diarrhea, Nausea, Vomiting, Dyspepsia, Stomach pain.

4.3. Indication of immediate medical attention and special treatment needed

Notes to Physician Treat symptomatically

SECTION 5. Fire-fighting measures

5.1. Extinguishing media

Suitable Extinguishing Media

Water spray. Carbon dioxide (CO₂). Foam. Dry powder.

Unsuitable extinguishing media

No information available.

5.2. Special hazards arising from the substance or mixture

Thermal decomposition can lead to release of irritating gases and vapors. Combustible material.

5.3. Advice for firefighters

Special protective equipment for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear

SECTION 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid contact with dusts/fumes/mists/vapors.

6.2. Environmental precautions

Prevent further leakage or spillage if safe to do so. Prevent entry into waterways, sewers, basements or confined areas.

6.3. Methods and materials for containment and cleaning up

Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13). If emergency, enforce internal emergency plan.

6.4. Reference to other sections

See sections 8 and 13 for additional information.

SECTION 7. Handling and storage

7.1. Precautions for Safe Handling

Handling

Avoid contact with skin, eyes and clothing. Handle in accordance with good industrial hygiene and safety practice. Do not breathe vapors/dust. Provide appropriate exhaust ventilation at places where dust is formed.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice

7.2. Conditions for safe storage, including any incompatibilities

Keep tightly closed in a dry and cool place. Protect from light. Keep in properly labeled containers. Keep at temperatures between 15°C and 30°C.

7.3. Specific end use(s)

Exposure Scenario	No information available
Other Guidelines	No information available

SECTION 8. Exposure controls/personal protection

8.1. Control parameters

Exposure Limits

This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Biological occupational exposure limits

Not Available

Derived No Effect Level (DNEL)

No information available.

Predicted No Effect Concentration (PNEC)

No information available.

8.2. Exposure controls

Engineering Measures

Provide engineering control, according to Teva Guidelines

Special Requirements

Avoid exposure of pregnant women starting from the second semester of pregnancy.

Personal protective equipment

Eye Protection

Approved safety goggles/glasses

Skin and Body Protection

Long sleeved clothing

Hand Protection

Rubber/latex/neoprene or other suitable chemical resistant gloves

Respiratory Protection

Approved full face respirator P3 or airline respirator

Environmental exposure controls

No information available

SECTION 9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	White to off- white , . crystalline powder.		
Odour	Odourless		
Odour Threshold	No information available		
pH	No information available.	Melting Point/Range	160 °C
Boiling Point/Range	No information available.	Flash Point	> 93 °C
Evaporation Rate	No information available	Flammability (solid, gas)	No information available.
Flammability Limits in Air		Vapor Pressure	No information available.
Upper	No information available.		
Lower	No information available.		
Vapor Density	No information available.	Relative Density	No information available.
Solubility	Practically insoluble in Dehydrated alcohol, Acetone, Acetonitrile, Chloroform, Ether. Sparingly soluble in Methanol.	Water Solubility	Freely soluble
Octanol/water Partition Coefficient (Log Kow)	-1	Autoignition Temperature	443 °C
Decomposition Temperature	No information available	Viscosity	No information available
Explosive Properties	No information available	Oxidizing Properties	No information available

9.2 Other information

Molecular Weight 441

SECTION 10. Stability and reactivity

10.1. Reactivity

No data available

10.2. Chemical stability

Stable under normal conditions

10.3. Possibility of hazardous reactions

Hazardous polymerization does not occur.

10.4. Conditions to avoid

Light, Direct sunlight, Heat, Moisture.

10.5. Incompatible materials

Oxidizing agents.

10.6. Hazardous decomposition products

Toxic fumes of: Carbon oxides, Nitrogen oxides (NOx).

SECTION 11. Toxicological information

11.1. Information on toxicological effects

Acute Toxicity

Product Information

LD50 Oral rat > 8500 mg/kg (anhydrous)
LD50 Oral mouse > 9100 mg/kg

Irritation: No information available.
Corrosivity: No information available
Sensitization: No information available
Eyes: N/A
Skin: May cause: Skin rash.
Inhalation: May cause: Cough, Infection, Nasal congestion, Influenza.
Ingestion: May cause: Diarrhea, Nausea, Vomiting, Dyspepsia, Stomach pain.

Chronic toxicity

Carcinogenicity

Not listed by IARC. Rats (male/female) up to 90 mg/kg/day/105W, mice (male/female) up to 135 mg/kg/day/92W: no evidence of a tumorigenic effect.

Reproductive Toxicity

Rats (male/female) up to 300 mg/kg/day: no adverse effects on reproductive performance. No teratogenic effects were seen in studies of pregnant mice, rats and rabbits

Mutagenic Effects

Not mutagenic in the Ames microbial mutagen test with or without metabolic activation. It was also negative in a forward mutation assay using Chinese hamster lung cells. Did not produce single strand DNA breaks in an in vitro alkaline elution rat hepatocyte assay. Did not produce increases in chromosomal aberrations in an in vitro test in Chinese hamster ovary cells or in an in vivo study in mouse bone marrow

STOT - repeated exposures

No information available

STOT - single exposure

No information available

Other information

Target Organ Effects

Cardiovascular system, Bone marrow.

Musculoskeletal System:

May cause: Muscle cramps.

Central nervous system:

May cause headache, May cause dizziness, May cause paresthesia, May cause vertigo.

Cardiovascular system:

May cause: Hypotension, Chest pain.

Body as a whole

May cause: Fatigue, Asthenia.

SECTION 12. Ecological information

12.1. Toxicity

Ecotoxicity effects

No information available

12.2. Persistence and degradability

No information available

12.3. Bioaccumulative potential

Not expected to bioaccumulate : Log Po/w <3 (EC) or <4 (GHS) Half-Life Elimination in Human: 12h

12.4. Mobility in soil

No information available

12.5. Results of PBT and vPvB assessment

No information available.

12.6. Other adverse effects

Endocrine Disruptor Information

Not available for data lacking

SECTION 13. Disposal considerations

13.1. Waste treatment methods

Waste from Residues/Unused Products

Dispose of in accordance with local regulations.

Contaminated Packaging

Empty containers should be taken for local recycling, recovery or waste disposal

SECTION 14. Transport information

14.1. UN-No	Not hazardous for transport
14.2. Proper Shipping Name	Not hazardous for transport
14.3 Transport hazard class(es) ADR / RID / ADN IMDG IATA / ICAO	Not hazardous for transport Not hazardous for transport Not hazardous for transport
14.4. Packing Group	Not hazardous for transport
14.5. Environmental hazards Marine Pollutant	No information Available
14.6. Special precautions for users Subsidiary Class EmS No. ADR/RID-Labels	No information available. No information available. No information available.
14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Technical name Ship type Annex II	Not available Not Available Not available

SECTION 15. Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

- Dir. 67/548/CE and 1999/45/CE and successive modifications
- Regulation 1907/2006/CE (REACH) and successive modifications
- Regulation 1272/2008 (CLP) and successive modifications
- Regulation 453/2010/CE Annex I
- D.Lgs. 81/2008 and successive modifications and Dir. 2009/161/UE

International Inventories

All of the components in the product are on the following Inventory lists.

TSCA	Listed
EINECS/ELINCS	-
DSL/NDSL	-
PICCS	-
ENCS	-
IECSC	-
AICS	-
KECL	-

Legend

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances

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

IECSC - China Inventory of Existing Chemical Substances

AICS - Australian Inventory of Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

15.2. Chemical Safety Assessment

No information available

SECTION 16. Other information

EU Directive 2001/58/EC

R-phrase(s)

R63 - Possible risk of harm to the unborn child

S-phrase(s)

S36/37/39 - Wear suitable protective clothing, gloves and eye/face protection

CLP/GHS - Regulation

Hazards Statements

H361d - Suspected of damaging the unborn child

Precautionary Statements

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

Training appropriate for workers is required to ensure protection of human health and environment.

NFPA

Health Hazard 1

Flammability 1

Stability 0

HMIS

1-1-0-C

Application/Drug Class Antihypertensive.

Source of data

SAX'S - DANGEROUS PROPERTIES OF INDUSTRIAL MATERIALS

VERSCHUEREN - HANDBOOK OF ENVIRONMENTAL DATA ON ORGANICS CHEMICALS

THE MERCK INDEX

KLEEMANN - PHARMACEUTICAL SUBSTANCES

R.T.E.C.S. - REGISTRY OF TOXIC EFFECTS OF CHEMICAL SUBSTANCES

STN DATA BANK

BRETHERRICK'S - HANDBOOK OF REACTIVE CHEMICAL HAZARDS

A.C.G.I.H. - AMERICAN CONFERENCE OF INDUSTRIAL HYGIENISTS

N.L.M. - NATIONAL LIBRARY OF MEDICINE

H.S.D.B. - HAZARDOUS SUBSTANCES DATA BANK

N.I.O.S.H. - NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

N.T.P. - NATIONAL TOXICOLOGY PROGRAM

I.A.R.C. - INTERNATIONAL AGENCY FOR RESEARCH ON CANCER

Chemspider database

ChemAdvisor

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Revision Note

Not applicable

Disclaimer

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End of Safety Data Sheet