



Valsartan

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Revision date: 15/08/2013

Version: 1.0

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

1.1. Product identifier

Product form	: Substance
Substance name	: Valsartan
Chemical name	: N-(1-Oxopentyl)-N-[[2'-(1H-tetrazol-5-yl)[1,1'biphenyl]-4-yl]methyl]-L-valine
CAS No.	: 137862-53-4
Product code	: VS
Formula	: C ₂₄ H ₂₉ N ₅ O ₃
Product group	: Pharmaceutical product

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

1.2.1. Relevant identified uses

Main use category	: Industrial use
Industrial/Professional use spec.	: isolated intermediate
Function or use category	: Antihypertensive

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Hetero drugs Ltd
7-2-A2, Hetero Corporate, Industrial Estate
500082 Hyderabad - INDIA
T 04023774009
drrama@heterodrugs.com - www.heterodrugs.com

1.4. Emergency telephone number

No additional information available

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Classification according to Directive 67/548/EEC or 1999/45/EC

Carc.Cat.3; R40


Full text of R-phrases: see section 16.

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP)	: 
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CLP Signal word	: Warning
Hazard statements (CLP)	: H302 - Harmful if swallowed H332 - Harmful if inhaled
Precautionary statements (CLP)	: P102 - Keep out of reach of children P103 - Read label before use P404 - Store in a closed container P403+P235 - Store in a cool and well-ventilated place.
EUH phrases	: EUH210 - Safety data sheet available on request EUH401 - To avoid risks to human health and the environment, comply with the instructions for use

2.3. Other hazards

No additional information available

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SECTION 3: Composition/information on ingredients

3.1. Substances

Name : Valsartan
CAS No. : 137862-53-4
EC no :
EC index no :

Name	Product identifier	%	Classification according to Directive 67/548/EEC
Ethyl acetate	(CAS No.)141-78-6 (EC no)205-500-4 (EC index no)607-022-00-5		F; R11 Xi; R36 R66 R67
Toluene	(CAS No.)108-88-3 (EC no)203-625-9 (EC index no)601-021-00-3		F; R11 Repr.Cat.3; R63 Xn; R48/20-65 Xi; R38 R67
Cyclohexane	(CAS No.)110-82-7 (EC no)203-806-2 (EC index no)601-017-00-1		F; R11 Xn; R65 Xi; R38 R67 N; R50-53
n-Hexane	(CAS No.)110-54-3 (EC no)203-777-6 (EC index no)601-037-00-0		F; R11 Repr.Cat.3; R62 Xn; R65-48/20 Xi; R38 R67 N; R51-53
(2R)-3-methyl-2-[pentanoyl[[2'-(1H-tetrazol-5-yl)biphenyl-4-yl]methyl]amino]butanoic acid			Not classified
(2S)-2-[butanoyl[[2'-(1H-tetrazol-5-yl)biphenyl-4-yl]methyl]amino]3-methyl butanoic acid.			Not classified
n-propyl acetate			Not classified
Ethyl propionate	(CAS No.)105-37-3 (EC no)203-291-4 (EC index no)607-028-00-8		F; R11
Dichloromethane	(CAS No.)75-09-2 (EC no)200-838-9 (EC index no)602-004-00-3		Carc.Cat.3; R40
Propan-2-ol	(CAS No.)67-63-0 (EC no)200-661-7 (EC index no)603-117-00-0		F; R11 Xi; R36 R67
Acetone	(CAS No.)67-64-1 (EC no)200-662-2 (EC index no)606-001-00-8		F; R11 Xi; R36 R66 R67
Ethanol	(CAS No.)64-17-5 (EC no)200-578-6 (EC index no)603-002-00-5		F; R11
Methanol	(CAS No.)67-56-1 (EC no)200-659-6 (EC index no)603-001-00-X		F; R11 T; R23/24/25-39/23/24/25
o-Xylene	(CAS No.)95-47-6 (EC no)202-422-2 (EC index no)601-022-00-9		R10 Xn; R20/21 Xi; R38

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Ethyl acetate	(CAS No.)141-78-6 (EC no)205-500-4 (EC index no)607-022-00-5		Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336
Toluene	(CAS No.)108-88-3 (EC no)203-625-9 (EC index no)601-021-00-3		Flam. Liq. 2, H225 Asp. Tox. 1, H304 Repr. 2, H361d Skin Irrit. 2, H315 STOT RE 2, H373 STOT SE 3, H336
Cyclohexane	(CAS No.)110-82-7 (EC no)203-806-2 (EC index no)601-017-00-1		Flam. Liq. 2, H225 Asp. Tox. 1, H304 Skin Irrit. 2, H315 STOT SE 3, H336 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

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Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
n-Hexane	(CAS No.)110-54-3 (EC no)203-777-6 (EC index no)601-037-00-0		Flam. Liq. 2, H225 Asp. Tox. 1, H304 Repr. 2, H361f Skin Irrit. 2, H315 STOT RE 2, H373 STOT SE 3, H336 Aquatic Chronic 2, H411
(2R)-3-methyl-2-[pentanoyl[[2'-(1H-tetrazol-5-yl)biphenyl-4-yl]methyl]amino]butanoic acid			Not classified
(2S)-2-[butanoyl[[2'-(1H-tetrazol-5-yl)biphenyl-4-yl]methyl]amino]3-methyl butanoic acid.			Not classified
n-propyl acetate			Not classified
Ethyl propionate	(CAS No.)105-37-3 (EC no)203-291-4 (EC index no)607-028-00-8		Flam. Liq. 2, H225
Dichloromethane	(CAS No.)75-09-2 (EC no)200-838-9 (EC index no)602-004-00-3		Carc. 2, H351
Propan-2-ol	(CAS No.)67-63-0 (EC no)200-661-7 (EC index no)603-117-00-0		Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336
Acetone	(CAS No.)67-64-1 (EC no)200-662-2 (EC index no)606-001-00-8		Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336
Ethanol	(CAS No.)64-17-5 (EC no)200-578-6 (EC index no)603-002-00-5		Flam. Liq. 2, H225
Methanol	(CAS No.)67-56-1 (EC no)200-659-6 (EC index no)603-001-00-X		Flam. Liq. 2, H225 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Inhalation), H331 Acute Tox. 3 (Oral), H301 STOT SE 1, H370
o-Xylene	(CAS No.)95-47-6 (EC no)202-422-2 (EC index no)601-022-00-9		Flam. Liq. 3, H226 Acute Tox. 4 (Dermal), H312 Acute Tox. 4 (Inhalation), H332 Skin Irrit. 2, H315

Full text of R-, H- and EUH-phrases: see section 16.

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
First-aid measures after inhalation	: Remove to fresh air and keep patient at rest. Seek medical attention immediately.
First-aid measures after skin contact	: When symptoms occur: rinse immediately with plenty of water. Remove contaminated clothing. Flush area with large amount of water. USE SOAP. seek medical attention.
First-aid measures after eye contact	: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
First-aid measures after ingestion	: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

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

Symptoms/injuries	: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
Symptoms/injuries after inhalation	: Remove to fresh air and keep patient at rest. Seek medical attention immediately.
Symptoms/injuries after skin contact	: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Symptoms/injuries after eye contact	: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
Symptoms/injuries after ingestion	: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

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SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Use carbon dioxide, dry chemical.

5.2. Special hazards arising from the substance or mixture

Fire hazard : Flammable with air within explosion limits Indirect fire hazard may be ignited by sparks
Gas/vapour spreads at floor level: ignition hazard.

Reactivity : Product is not explosive.

5.3. Advice for firefighters

No additional information available

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

No additional information available

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

No additional information available

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Wipe up with a damp cloth and place in container for disposal. Clean spill area thoroughly.

Other information : Wash clothing and equipment after handling.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Do not eat, drink or smoke when using this product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Pack in air tight containers. Store the material at temperature below 25°C.

Storage temperature : 25 °C

Special rules on packaging : Triple laminated aluminium package.

Packaging materials : triple laminated aluminium package.

7.3. Specific end use(s)

Fabric Refresher.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls : Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal protective equipment : Safety glasses. Protective goggles. Protective clothing. Gas mask with filter type A.



Materials for protective clothing : Chloroprene rubber nitrile rubber.

Hand protection : Gloves.

Eye protection : Safety glasses.

Skin and body protection : Protective clothing.

Respiratory protection : Gas mask with filter type A.

Other information : The present safety data sheet is consistent with the specific conditions relied on to justify the registration of the substance as isolated intermediate.

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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: White or almost white, hygroscopic powder.
Molecular mass	: 435.5 g/mol
Colour	: White.
Odour	: Odourless.
Odour threshold	: No data available
pH	: No data available
Melting point	: No data available
Solidification point	: No data available
Boiling point	: No data available
Flash point	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Flammability (solid, gas)	: No data available
Explosive limits	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Practically insoluble in water, freely soluble in ethanol and sparingly soluble in methylene chloride.
Log Pow	: No data available
Log Kow	: No data available
Self ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Product is not explosive.

10.2. Chemical stability

Stable under defined conditions.

10.3. Possibility of hazardous reactions

No additional information available

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

As a precautionary measure. Keep away from strong oxidizers.

10.6. Hazardous decomposition products

No additional information available

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	: Not classified
Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified

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Specific target organ toxicity (single exposure) : Not classified

Specific target organ toxicity (repeated exposure) : Not classified

Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : Practically insoluble in water, freely soluble in ethanol and sparingly soluble in methylene chloride.

Ecology - air : Not dangerous for the ozone layer(1999/45/EC).

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

Valsartan(137862-53-4)

Bioaccumulative potential	The substance has low potential for bioaccumulation.
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12.4. Mobility in soil

Valsartan(137862-53-4)

Ecology - soil	The substance has moderate mobility in groundwater. The substance has moderate mobility in soil.
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12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Additional information : Wash clothing and equipment after handling.

Ecology - waste materials : Take up liquid spill into absorbent material-Scoop absorbed substance into closing containers.

SECTION 14: Transport information

No dangerous good in sense of transport regulations.

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

Contains no REACH candidate substance

EURAL code : 20 01 32

CESIO recommendations : This surfactant complies with the biodegradability criteria as laid down in Regulation (EC) No.648/2004 on detergents. Data to support this assertion are held at the disposal of the competent authorities of the Member States and will be made available to them, at their direct request or at the request of a detergent manufacturer.

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No additional information available

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SECTION 16: Other information

Full text of R-, H- and EUH-phrases:

Acute Tox. 3 (Dermal)	Acute toxicity (dermal) Category 3
Acute Tox. 3 (Inhalation)	Acute toxicity (inhalation) Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral) Category 3
Acute Tox. 4 (Dermal)	Acute toxicity (dermal) Category 4
Acute Tox. 4 (Inhalation)	Acute toxicity (inhalation) Category 4
Aquatic Acute 1	Hazardous to the aquatic environment - Acute Hazard Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment - Chronic Hazard Category 1
Aquatic Chronic 2	Hazardous to the aquatic environment - Chronic Hazard Category 2
Asp. Tox. 1	Aspiration hazard Category 1
Carc. 2	Carcinogenicity Category 2
Eye Irrit. 2	Serious eye damage/eye irritation Category 2
Flam. Liq. 2	Flammable liquids Category 2
Flam. Liq. 3	Flammable liquids Category 3
Repr. 2	Reproductive toxicity Category 2
Repr. 2	Reproductive toxicity Category 2
Skin Irrit. 2	skin corrosion/irritation Category 2
STOT RE 2	Specific target organ toxicity (repeated exposure) Category 2
STOT SE 1	Specific target organ toxicity (single exposure) Category 1
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H225	Highly flammable liquid and vapour
H226	Flammable liquid and vapour
H301	Toxic if swallowed
H304	May be fatal if swallowed and enters airways
H311	Toxic in contact with skin
H312	Harmful in contact with skin
H315	Causes skin irritation
H319	Causes serious eye irritation
H331	Toxic if inhaled
H332	Harmful if inhaled
H336	May cause drowsiness or dizziness
H351	Suspected of causing cancer
H361d	Suspected of damaging the unborn child.
H361f	Suspected of damaging fertility.
H370	Causes damage to organs
H373	May cause damage to organs through prolonged or repeated exposure
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects
H411	Toxic to aquatic life with long lasting effects
R10	Flammable.
R11	Highly flammable.
R20/21	Harmful by inhalation and in contact with skin.
R23/24/25	Toxic by inhalation, in contact with skin and if swallowed.
R36	Irritating to eyes.
R38	Irritating to skin.
R39/23/24/25	Toxic: danger of very serious irreversible effects through inhalation, in contact with skin and if swallowed.
R40	Limited evidence of a carcinogenic effect
R48/20	Harmful: danger of serious damage to health by prolonged exposure through inhalation.
R50	Very toxic to aquatic organisms.
R51	Toxic to aquatic organisms.
R53	May cause long-term adverse effects in the aquatic environment.
R62	Possible risk of impaired fertility.
R63	Possible risk of harm to the unborn child.
R65	Harmful: may cause lung damage if swallowed.
R66	Repeated exposure may cause skin dryness or cracking.
R67	Vapours may cause drowsiness and dizziness.

SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.