

DAIICHI SANKYO EUROPE GmbH
81379 München

Date printed 07.04.2014, Revision 07.04.2014

Version 01

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SECTION 1: Identification of the substance / preparation and of the company

1.1 Product identifier

Olmesartan medoxomil / Amlodipine besylate / Hydrochlorothiazide film coated tablets - 20/5/12,5mg, 40/5/12,5 mg, 40/5/25mg, 40/10/12,5mg, 40/10/25mg:

TRIBENZOR

CAPENON HCT

SEVIKAR HCT

TRILOVASC

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

1.2.1 Relevant uses

Finished medicinal product

1.2.2 Uses advised against

None known.

1.3 Details of the supplier of the safety data sheet

Company

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81379 München / GERMANY
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Homepage www.daiichi-sankyo.eu
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Address enquiries to

Technical information

service@daiichi-sankyo.eu

Safety Data Sheet

sdb@chemiebuero.de

1.4 Emergency phone

Company

+49 89 78 08 - 0

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

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

see SECTION 16

2.1.2 Classification according to Regulation 67/548/EEC or 1999/45/EC

Xn, carcinogen category 3 - R 40: Limited evidence of a carcinogenic effect.
Sensitizing. - R 43: May cause sensitisation by skin contact.

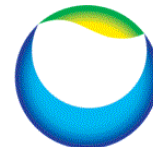
2.2 Label elements

The product is classified and required to be labelled in accordance with EC-Directives
This preparation is a medicinal product and hence exempt from the regulation 1999/45/EEC.

2.3 Other hazards

Other hazards

none



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SECTION 3: Composition / Information on ingredients

Product-type:

The product is a mixture.

Range [%]	Substance
1 - 10	3-Ethyl-5-methyl (4RS)-2-[(2-aminoethoxy) methyl]-4-(2-chlorophenyl)-6-methyl-1,4-dihydro pyridine-3,5-dicarboxylate benzene sulphonate CAS: 111470-99-6 GHS/CLP: Acute Tox. 4: H302 - Skin Corr. 1C: H314 EEC: Xn, R 22-36/37/38
1 - 10	Hydrochlorothiazide CAS: 58-93-5, EINECS/ELINCS: 200-403-3 GHS/CLP: Carc. 2: H351 - Skin Sens. 1: H317 EEC: Xn, R 40-43

Comment on component parts

Substances of Very High Concern - SVHC: substances are not contained or are below 0,1%.
For full text of H-statements and R-phrases: see SECTION 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General information

Change soaked clothing.

Inhalation

Not required under normal conditions.

Skin contact

In case of contact with skin wash off immediately with soap and water.
Consult a doctor if skin irritation persists.

Eye contact

Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice/attention.

Ingestion

After unintentional swallowing, induce vomiting only if fully conscious.
Rinse out mouth and give plenty of water to drink.
Seek medical advice.

4.2 Most important symptoms and effects, both acute and delayed

No information available.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.
Forward this sheet to the doctor.

SECTION 5: Fire-fighting measures

5.1 Extinguishing media

Suitable extinguishing media

All extinguishing media are suitable but method must take into account the surrounding area to minimize dispersion.

Extinguishing media that must not be used

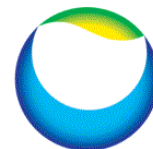
none

5.2 Special hazards arising from the substance or mixture

Unknown risk of formation of toxic pyrolysis products.
Carbon monoxide (CO).
Nitrogen oxides (NOx).

5.3 Advice for firefighters

Use self-contained breathing apparatus.
Do not inhale explosion and/or combustion gases.
Cool containers at risk with water spray jet.
Fire residues and contaminated firefighting water must be disposed of in accordance with the local regulations.



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SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Avoid dust formation.
Ensure adequate ventilation.

6.2 Environmental precautions

Do not discharge into the drains/surface waters/groundwater.

6.3 Methods and material for containment and cleaning up

Take up mechanically.
Avoid raising dust.
Dispose of absorbed material in accordance within the regulations.

6.4 Reference to other sections

See SECTION 8+13

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Use only in well-ventilated areas.
Avoid the formation and deposition of dust.
Provide suitable vacuuming at the processing machines.
Dust can form an explosive mixture with air.
Keep away from all sources of ignition - Refrain from smoking.
Contaminated work clothing should not be allowed out of the workplace.
Do not eat, drink or smoke when using this product.
Wash hands before breaks and after work.
Use barrier skin cream.
Take off contaminated clothing and wash before reuse.

7.2 Conditions for safe storage, including any incompatibilities

Keep only in original container.
Do not store together with oxidizing agents.
Store in a dry place.
Keep container in a well-ventilated place.
Keep container tightly closed.

7.3 Specific end use(s)

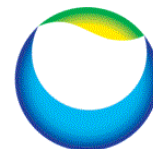
See product use, SECTION 1.2

SECTION 8: Exposure controls / personal protection

Ingredients with occupational exposure limits to be monitored (GB)

8.1 Control parameters

not applicable



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8.2 Exposure controls

Additional advice on system design	Ensure adequate ventilation on workstation. To pay attention to dust limit value (ACGIH-2011: 10 mg/m ³ particle inhalable; 3 mg/m ³ particle respirable).
Eye protection	Not required under normal conditions. Safety glasses.
Hand protection	Not required under normal conditions. The details concerned are recommendations. Please contact the glove supplier for further information. In full contact: butyl rubber, > 120 min (EN 374)
Skin protection	Not required under normal conditions.
Other	Avoid contact with eyes and skin. Do not inhale dust. Personal protective equipment should be selected specifically for the working place, depending on concentration and quantity of the hazardous substances handled. The resistance of these equipments to chemicals should be ascertained with the respective supplier.
Respiratory protection	Respiratory protection in the case of dust formation. Short term: filter apparatus, filter P2.
Thermal hazards	No information available.
Delimitation and monitoring of the environmental exposition	not determined

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Form	tablet
Color	various
Odor	odourless
Odour threshold	not determined
pH-value	not determined
pH-value [1%]	not determined
Boiling point [°C]	not applicable
Flash point [°C]	not applicable
Flammability [°C]	not determined
Lower explosion limit	not applicable
Upper explosion limit	not applicable
Oxidizing properties	no
Vapour pressure/gas pressure [kPa]	not applicable
Density [g/ml]	not determined
Bulk density [kg/m³]	not determined
Solubility in water	partially soluble
Partition coefficient [n-octanol/water]	not determined
Viscosity	not applicable
Relative vapour density determined in air	not applicable
Evaporation speed	not applicable
Melting point [°C]	not determined
Autoignition temperature [°C]	not determined
Decomposition temperature [°C]	not applicable

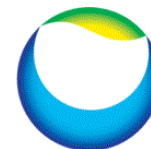
9.2 Other information

none

SECTION 10: Stability and reactivity

10.1 Reactivity

No dangerous reactions known if used as directed.



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10.2 Chemical stability

Stable under normal ambient conditions (ambient temperature).

10.3 Possibility of hazardous reactions

Reactions with strong oxidizing agents.

10.4 Conditions to avoid

Strong heating.

10.5 Incompatible materials

No information available.

10.6 Hazardous decomposition products

No hazardous decomposition products known.

SECTION 11: Toxicological information**11.1 Information on toxicological effects****Acute toxicity**

Range [%]	Substance
1 - 10	Hydrochlorothiazide, CAS: 58-93-5
	LD50, oral, mouse: 1175 mg/kg.
	LD50, oral, Rat: 2750 mg/kg.

Serious eye damage/irritation	not determined
Skin corrosion/irritation	not determined
Respiratory or skin sensitisation	not determined
Specific target organ toxicity — single exposure	not determined
Specific target organ toxicity — repeated exposure	not determined
Mutagenicity	not determined
Reproduction toxicity	not determined
Carcinogenicity	not determined
General remarks	

The product was classified on the basis of the calculation procedure of the preparation directive.

Toxicological data of complete product are not available.

SECTION 12: Ecological information**12.1 Toxicity**

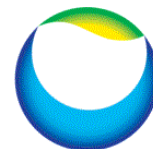
Range [%]	Substance
1 - 10	Hydrochlorothiazide, CAS: 58-93-5
	LC50, fish: > 100 mg/l.
	EC50, Daphnia magna: > 100 mg/l.

12.2 Persistence and degradability

Behaviour in environment compartments	not determined
Behaviour in sewage plant	not applicable
Biological degradability	not applicable

12.3 Bioaccumulative potential

No information available.



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12.4 Mobility in soil

No information available.

12.5 Results of PBT and vPvB assessment

No information available.

12.6 Other adverse effects

Ecological data of complete product are not available.

No classification on the basis of the calculation procedure of the preparation directive.

SECTION 13: Disposal considerations**13.1 Waste treatment methods**

Waste material must be disposed of in accordance with the Directive on waste 2008/98/EC as well as other national and local regulations. It is not possible to determine a waste code for this product in accordance with the European Waste Catalogue (EWC) since it is only possible to classify it according to how it is used by the customer. The waste code is to be determined within the EU in liaison with the waste-disposal operator.

Product

Dispose of as hazardous waste.
For recycling, consult manufacturer.

Waste no. (recommended)

180109

Contaminated packaging

Packaging that cannot be cleaned should be disposed of as for product.
Untampered packaging may be taken for recycling.

Waste no. (recommended)

150110*
150101
150104
150102

SECTION 14: Transport information**14.1 UN number**

See SECTION 14.2 in accordance with UN shipping name

14.2 UN proper shipping name

Transport by land according to ADR/RID NO DANGEROUS GOODS

Inland navigation (ADN) NO DANGEROUS GOODS

Marine transport in accordance with IMDG NOT CLASSIFIED AS "DANGEROUS GOODS"

Air transport in accordance with IATA NOT CLASSIFIED AS "DANGEROUS GOODS"

14.3 Transport hazard class(es)

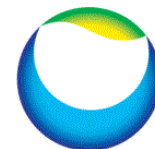
See SECTION 14.2 in accordance with UN shipping name

14.4 Packing group

See SECTION 14.2 in accordance with UN shipping name

14.5 Environmental hazards

See SECTION 14.2 in accordance with UN shipping name



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14.6 Special precautions for user

Relevant information under SECTION 6 to 8.

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

not applicable

SECTION 15: Regulatory information

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

EEC-REGULATIONS 1967/548 (1999/45); 1991/689 (2001/118); 1999/13; 2004/42; 648/2004; 1907/2006 (Reach); 1272/2008; 75/324/EEC (2008/47/EC); 453/2010/EC

TRANSPORT-REGULATIONS DOT-Classification, ADR (2013); IMDG-Code (2013, 36. Amdt.); IATA-DGR (2013).

NATIONAL REGULATIONS (GB): EH40/2005 Workplace exposure limits (Second edition, published December 2011).
CHIP 3/ CHIP 4

- Observe employment restrictions for people not applicable

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 given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release in the work place area. MSDSs are not intended to be used by our patients as a replacement for or as a complement to prescribing information (such as package inserts) or the advice of a healthcare professional. If you are taking any of our products as medications, you should review the package inserts for the product for useful information on formulation, mode of action, use precautions and side effects.

- VOC (1999/13/CE) not applicable

15.2 Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information

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

Hazard pictograms



Signal word

WARNING

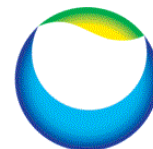
Carc. 2: H351 Suspected of causing cancer.
Skin Sens. 1: H317 May cause an allergic skin reaction.
Skin Irrit. 2: H315 Causes skin irritation.
Eye Irrit. 2: H319 Causes serious eye irritation.
STOT SE 3: H335 May cause respiratory irritation.

16.2 R-phrases (SECTION 3)

R 40: Limited evidence of a carcinogenic effect.
R 43: May cause sensitisation by skin contact.
R 22: Harmful if swallowed.
R 36/37/38: Irritating to eyes, respiratory system and skin.

16.3 Hazard statements (SECTION 3)

H314 Causes severe skin burns and eye damage.
H302 Harmful if swallowed.
H317 May cause an allergic skin reaction.
H351 Suspected of causing cancer.



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16.4 Abbreviations and acronyms:

ADR = Accord européen relatif au transport international des marchandises Dangereuses par Route
 RID = Règlement concernant le transport international ferroviaire de marchandises dangereuses
 ADN = Accord européen relatif au transport international des marchandises dangereuses par voie de navigation intérieure
 CAS = Chemical Abstracts Service
 CLP = Classification, Labelling and Packaging
 DMEL = Derived Minimum Effect Level
 DNEL = Derived No Effect Level
 EC50 = Median effective concentration
 ECB = European Chemicals Bureau
 EEC = European Economic Community
 EINECS = European Inventory of Existing Commercial Chemical Substances
 ELINCS = European List of Notified Chemical Substances
 GHS = Globally Harmonized System of Classification and Labelling of Chemicals
 IATA = International Air Transport Association
 IBC-Code = International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk
 IC50 = Inhibition concentration, 50%
 IMDG = International Maritime Code for Dangerous Goods
 IUCLID = International Uniform Chemical Information Database
 LC50 = Lethal concentration, 50%
 LD50 = Median lethal dose
 MARPOL = International Convention for the Prevention of Marine Pollution from Ships
 PBT = Persistent, Bioaccumulative and Toxic substance
 PNEC = Predicted No-Effect Concentration
 REACH = Registration, Evaluation, Authorisation and Restriction of Chemicals
 TLV@/TWA = Threshold limit value – time-weighted average
 TLV@STEL = Threshold limit value – short-time exposure limit
 VOC = Volatile Organic Compounds
 vPvB = very Persistent and very Bioaccumulative

16.5 Other information

Customs Tariff	not determined
Modified position	none

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