

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 film coated tablets -  
20/5mg, 20/10mg, 40/5mg, 40/10mg:**

**AZOR**

**AZOREN**

**CAPENON**

**SEVIKAR**

**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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**Safety Data Sheet**

[sdb@chemiebuero.de](mailto: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]**

No classification.

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

No classification.

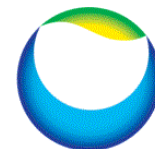
**2.2 Label elements**

The product does not require a hazard warning label 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 - <20	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

**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.

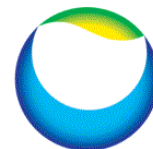
**4.3 Indication of any immediate medical attention and special treatment needed**Treat symptomatically.  
Forward this sheet to the doctor.**SECTION 5: Fire-fighting measures****5.1 Extinguishing media****Suitable extinguishing media**

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.**SECTION 6: Accidental release measures****6.1 Personal precautions, protective equipment and emergency procedures**Avoid dust formation.  
Ensure adequate ventilation.



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## 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)

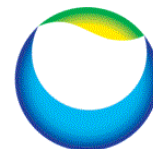
See product use, SECTION 1.2

# SECTION 8: Exposure controls / personal protection

## 8.1 Control parameters

Ingredients with occupational  
exposure limits to be monitored (GB)

not applicable

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**8.2 Exposure controls**

<b>Additional advice on system design</b>	Ensure adequate ventilation on workstation. To pay attention to dust limit value (ACGIH-2011: 10 mg/m <sup>3</sup> particle inhalable; 3 mg/m <sup>3</sup> particle respirable).
<b>Eye protection</b>	Not required under normal conditions. Safety glasses.
<b>Hand protection</b>	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)
<b>Skin protection</b>	Not required under normal conditions.
<b>Other</b>	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.
<b>Respiratory protection</b>	Respiratory protection in the case of dust formation. Short term: filter apparatus, filter P2.
<b>Thermal hazards</b>	No information available.
<b>Delimitation and monitoring of the environmental exposition</b>	not determined

**SECTION 9: Physical and chemical properties****9.1 Information on basic physical and chemical properties**

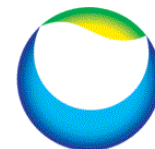
<b>Form</b>	tablet
<b>Color</b>	various
<b>Odor</b>	odourless
<b>Odour threshold</b>	not determined
<b>pH-value</b>	not determined
<b>pH-value [1%]</b>	not determined
<b>Boiling point [°C]</b>	not applicable
<b>Flash point [°C]</b>	not applicable
<b>Flammability [°C]</b>	not determined
<b>Lower explosion limit</b>	not applicable
<b>Upper explosion limit</b>	not applicable
<b>Oxidizing properties</b>	no
<b>Vapour pressure/gas pressure [kPa]</b>	not applicable
<b>Density [g/ml]</b>	not determined
<b>Bulk density [kg/m<sup>3</sup>]</b>	not determined
<b>Solubility in water</b>	partially soluble
<b>Partition coefficient [n-octanol/water]</b>	not determined
<b>Viscosity</b>	not applicable
<b>Relative vapour density determined in air</b>	not applicable
<b>Evaporation speed</b>	not applicable
<b>Melting point [°C]</b>	not determined
<b>Autoignition temperature [°C]</b>	not determined
<b>Decomposition temperature [°C]</b>	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**

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

**General remarks**

No classification 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****12.2 Persistence and degradability**

<b>Behaviour in environment compartments</b>	not determined
<b>Behaviour in sewage plant</b>	not applicable
<b>Biological degradability</b>	not applicable

**12.3 Bioaccumulative potential**

No information available.

**12.4 Mobility in soil**

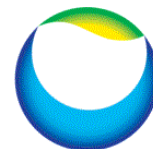
No information available.

**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.



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### 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

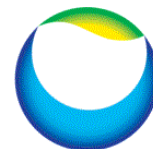
See SECTION 14.2 in accordance with UN shipping name

#### 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

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**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 R-phrases (SECTION 3)**

R 22: Harmful if swallowed.  
R 36/37/38: Irritating to eyes, respiratory system and skin.

**16.2 Hazard statements (SECTION 3)**

H314 Causes severe skin burns and eye damage.  
H302 Harmful if swallowed.

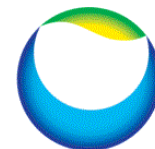
**16.3 Abbreviations and acronyms:**

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

**16.4 Other information**

**Customs Tariff** not determined

**Classification procedure**



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Modified position

none

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