Version	Revision Date:	SDS Number:	Date of last issue: 26.07.2017
3.0	29.01.2019	20559	Date of first issue: 26.07.2017

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifier

BETALOC® SOLUTION

Details of the supplier of the safety data sheet : ASTRAZENECA PTY LTD
PO Box 131
66 Talavera Rd, North Ryde
NSW 2113
AUSTRALIA
+61 2 9978 3500

SafetyDataSheets.AlderleyPark@astrazeneca.com

Emergency Telephone
+44 (0) 1235 239 670

Alternative Names
Betaloc i.v. injection 1 mg/mL
Metoprolol tartrate injection 1 mg/mL
Metoprolol solution

CAS No. : Not applicable

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

Use of the Substance/Mixture : control of tachyarrhythmias, especially supraventricular tachyarrhythmias

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Not a hazardous substance or mixture.

GHS label elements

Not a hazardous substance or mixture.

Other hazards which do not result in classification

May cause lowering of blood pressure (resulting in dizziness, fatigue and headache), change in heart rhythm and gastrointestinal disorders.
Rare cases of skin sensitisation have been reported.
See Section 11.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Metoprolol tartrate	56392-17-7	0.1

SECTION 4. FIRST AID MEASURES

If inhaled : Remove patient from exposure.
Obtain medical attention if ill effects occur.

In case of skin contact : Wash skin with soap and water.

In case of eye contact	:	Irrigate with eyewash solution or clean water, holding the eyelids apart, for at least 10 minutes. Obtain medical attention if ill effects remain.
If swallowed	:	Wash out mouth with water and give 200-300ml of water to drink. Obtain medical attention if ill effects occur. Do NOT induce vomiting as a First-Aid measure.
Most important symptoms and effects, both acute and delayed	:	Refer to sections 2 and 11
Notes to physician	:	Symptomatic treatment and supportive therapy as indicated. For further information consult the prescribing information.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media	:	Use suitable extinguishing media for the surrounding fire.
Unsuitable extinguishing media	:	-
Specific hazards during firefighting	:	Low fire hazard.
Special protective equipment for firefighters	:	A self contained breathing apparatus and suitable protective clothing should be worn in fire conditions.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Ensure suitable personal protection during removal of spillages. See Section 8.
Environmental precautions	:	Prevent entry into drains, sewers or watercourses.
Methods and materials for containment and cleaning up	:	Clear up spillages. Transfer to a container for disposal. Wash the spillage area with water. See section 13.

SECTION 7. HANDLING AND STORAGE

Advice on safe handling	:	Avoid contact with skin and eyes.
Conditions for safe storage	:	Keep container tightly closed. Protect from light.
Recommended storage temperature	:	< 30 °C

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Metoprolol tartrate	56392-17-7	TWA	0.5 mg/m3	COM; HYG

Engineering measures : The specific controls will depend on local circumstances and should be based on the risk assessment. Appropriate controls to reduce exposure may include engineering controls, for example ventilation, procedural controls and the use of personal protection equipment.

Prevent entry into drains, sewers or watercourses.

Personal protective equipment

Respiratory protection : Use a negative pressure air purifying respirator (half face mask) with filter class A if the risk assessment does not support the selection of other protection.

Eye protection : Use safety glasses to protect against direct contact with the product if the risk assessment does not support the selection of other protection.

Skin and body protection : Use protective clothing to protect against direct contact with the product if the risk assessment does not support the selection of other protection. Use chemical protective gloves with a permeation time greater than the activity duration. Take note of the information given by the PPE producer/supplier concerning permeability and breakthrough times and special workplace conditions.

Protective measures : Decisions about whether the use of personal protective equipment (PPE) is appropriate as part of the control strategy should be based on the workplace risk assessment and should take account of local legislative requirements for selection and use. There are multiple factors that will affect the specific requirements such as amount and concentration of the material, duration of exposure, frequency of exposure, external environmental conditions, the task, the user etc. All the information above should not be used in isolation and should be considered in the context of the workplace risk assessment on a case by case basis.

The recommended personal protective equipment (PPE) is based on preventing the potential adverse health effects from exposure to the active pharmaceutical ingredient (API). The risk of exposure to the API in the formulation/product needs to be taken into consideration.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	Aqueous solution
Colour	:	No data available
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	No data available
Melting point/range	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Explosive properties	:	No data available

Oxidizing properties : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : No known reactivity hazard under normal conditions.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : None known.

Conditions to avoid : No conditions producing hazardous situations known.

Incompatible materials : None known.

Hazardous decomposition products : No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

11.1 Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Remarks: Low acute oral toxicity.

Components:

Metoprolol tartrate:

Acute oral toxicity : LD50 Oral (Rat): 3,090 - 4,670 mg/kg

Acute inhalation toxicity : Remarks: May cause effects as described under single exposure.(STOT)

Acute dermal toxicity : Remarks: No information available.

11.2 Skin corrosion/irritation

Not classified based on available information.

Product:

Remarks : May cause slight skin irritation.

Components:

Metoprolol tartrate:

Result : Irritating to skin.

11.3 Serious eye damage/eye irritation

Not classified based on available information.

Product:

Remarks : May cause slight eye irritation.

Components:

Metoprolol tartrate:

Remarks : May cause eye irritation.
May cause excessive watering of the eye (lachrymation).

11.4 Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Metoprolol tartrate:

Remarks : Rare cases of skin sensitisation have been reported.

Chronic toxicity

11.5 Germ cell mutagenicity

Not classified based on available information.

Components:

Metoprolol tartrate:

Germ cell mutagenicity - Assessment : There is no evidence of genotoxic potential in in vitro and in vivo tests.

11.6 Carcinogenicity

Not classified based on available information.

Components:

Metoprolol tartrate:

Carcinogenicity - Assessment : No evidence of carcinogenicity in animal studies.

11.7 Reproductive toxicity

Not classified based on available information.

Components:

Metoprolol tartrate:

Reproductive toxicity - Assessment : Studies in animals have shown that repeated doses produce embryo/foetotoxic effects., By analogy with other beta-blockers:, Positive evidence of adverse effects on development from human epidemiological studies., Foetal and neonatal toxicity in babies born to women receiving treatment during pregnancy has been reported.
Effects on or via lactation

11.8 STOT - single exposure

Not classified based on available information.

Components:

Metoprolol tartrate:

Exposure routes	:	Inhalation, Oral
Remarks	:	May cause lowering of blood pressure (resulting in dizziness, fatigue and headache), change in heart rhythm and gastrointestinal disorders.

11.9 STOT - repeated exposure

Not classified based on available information.

Components:

Metoprolol tartrate:

Remarks	:	May cause effects as described under single exposure.(STOT)

11.10 Aspiration toxicity

Not classified based on available information.

Components:

Metoprolol tartrate:

No information available.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Product:

Ecotoxicology Assessment

Chronic aquatic toxicity	:	This product has no known ecotoxicological effects. Remarks: No information on this formulation. Information refers to Metoprolol succinate

Components:

Metoprolol tartrate:

Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): 130 mg/l Exposure time: 96 H Test Type: static test Method: OECD Test Guideline 203 NOEC (Oncorhynchus mykiss (rainbow trout)): 32 mg/l Exposure time: 96 H Test Type: static test Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 120 mg/l Exposure time: 48 H Test Type: static test Method: OECD Test Guideline 202

NOEC (Daphnia magna (Water flea)): 30 mg/l
Exposure time: 48 H
Test Type: static test
Method: OECD Test Guideline 202

Toxicity to algae : EC50 (Selenastrum capricornutum (green algae)): 58.3 mg/l
Exposure time: 72 H
Test Type: Growth inhibition
Method: OECD Test Guideline 201

NOEC (Selenastrum capricornutum (green algae)): 7.5 mg/l
Exposure time: 72 H
Test Type: Growth inhibition
Method: OECD Test Guideline 201

Toxicity to microorganisms : EC50 (Sewage sludge organisms): > 100 mg/l
Exposure time: 3 H
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

Ecotoxicology Assessment

Chronic aquatic toxicity : Harmful to aquatic life with long lasting effects.
Remarks: Information refers to
Metoprolol succinate

Persistence and degradability

Components:

Metoprolol tartrate:

Biodegradability : Result: not rapidly degradable

Bioaccumulative potential

Components:

Metoprolol tartrate:

Bioaccumulation : Remarks: The substance has low potential for bioaccumulation.

Mobility in soil

Components:

Metoprolol tartrate:

Mobility : Remarks: Water solubility >= 1 mg/l.

Distribution among environmental compartments : Remarks: No information available.

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues	:	Disposal should be in accordance with local, state or national legislation.
Contaminated packaging	:	Empty container will retain product residue. Observe all hazard precautions.

SECTION 14. TRANSPORT INFORMATION

Not classified as dangerous in the meaning of transport regulations.

SECTION 15. REGULATORY INFORMATION

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

In order to comply with legal duties it is necessary to consult local and national legislation.

Standard for the Uniform Scheduling of Medicines and Poisons	:	No poison schedule number allocated
Prohibition/Licensing Requirements	:	There is no applicable prohibition or notification/licensing requirements, including for carcinogens under Commonwealth, State or Territory legislation.

The components of this product are reported in the following inventories:

REACH	:	Not in compliance with the inventory
DSL	:	This product contains the following components that are not on the Canadian DSL nor NDSL. Metoprolol tartrate
AICS	:	Not in compliance with the inventory
ENCS	:	Not in compliance with the inventory
ISHL	:	Not in compliance with the inventory

IECSC	:	Not in compliance with the inventory
TCSI	:	Not in compliance with the inventory
TSCA	:	Not On TSCA Inventory

SECTION 16. OTHER INFORMATION

Further information

Revision Date	:	29.01.2019
Other information	:	Full Review - minor changes 3 15
Date format	:	dd.mm.yyyy

Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; 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; COM – In-house occupational exposure limit; CPR - Controlled Products Regulations; 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; HYG – Analytical method for occupational exposure monitoring; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; 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; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); 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; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; (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; Sen – Capable of causing respiratory sensitization; Sk – Can be absorbed through skin, thus contributing to systemic effects; STEL – Short-term exposure limit 15-minutes time-weighted average; TLV – Threshold Limit Value (ACGIH); TLV-C – Threshold Limit Value Ceiling limit (ACGIH); TSCA - Toxic Substances Control Act (United States); TWA – Long-term exposure limit 8h time-weighted average; 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

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 and is

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