

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date: 09.02.2021

Version number: 1.0

Revision: 09.02.2021

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

1.1 Product identifier

Trade name: Rocuronium RTS

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

No further relevant information available.

Application of the substance / the preparation: Analytical sample

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:

Fresenius Kabi Austria GmbH
Parkring 18
8074 Grambach
Tel.: +43-(0)316-249-1210
Fax: +43 (0)316-249-1422
Email: info-atgr@fresenius-kabi.com
www.fresenius-kabi.com

Further information obtainable from: Fresenius Kabi Austria GmbH

1.4 Emergency telephone number:

+43-(0)316-249-1210 (während des Geschäftszeiten / during business hours)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture:

Classification according to Regulation (EC) No 1272/2008:

The product is not classified, according to the CLP regulation.

2.2 Label elements:

Labelling according to Regulation (EC) No 1272/2008: Void**Hazard pictograms:** Void**Signal word:** Void**Hazard statements:** Void

2.3 Other hazards:

Results of PBT and vPvB assessment:**PBT:** Not applicable.**vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Description: Mixture of substances listed below with nonhazardous additions.**Dangerous components:**

CAS: 119302-91-9 1-[17beta-(acetyloxy)-3alpha-hydroxy-2beta-(4-morpholinyl)-5alpha-EC number: 601-597-6 androstan-16beta-yl]-1-(2propenyl)pyrrolidinium bromide ≤2.5%

 Acute Tox. 2, H330;  Acute Tox. 4, H302; Acute Tox. 4, H312

Additional information: For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures:

General information:

Take affected persons out into the fresh air.

Do not leave affected persons unattended.

After inhalation: Supply fresh air or oxygen; call for doctor.**After skin contact:**

Immediately wash with water and soap and rinse thoroughly.

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Call a doctor immediately.

After eye contact:

Rinse opened eye for several minutes under running water.

Call a doctor immediately.

After swallowing: Call a doctor immediately.**4.2 Most important symptoms and effects, both acute and delayed:**

No further relevant information available.

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

No further relevant information available.

SECTION 5: Firefighting measures**5.1 Extinguishing media:****Suitable extinguishing agents:**CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.**5.2 Special hazards arising from the substance or mixture:** No further relevant information available.**5.3 Advice for firefighters:****Protective equipment:**

Mouth respiratory protective device.

Do not inhale explosion gases or combustion gases.

Additional information:

Collect contaminated fire fighting water separately. It must not enter the sewage system.

SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures:**

Use respiratory protective device against the effects of fumes/dust/aerosol.

Wear protective clothing.

Ensure adequate ventilation.

6.2 Environmental precautions: Do not allow product to reach sewage system or any water course.**6.3 Methods and material for containment and cleaning up:**

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Ensure adequate ventilation.

6.4 Reference to other sections:

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7: Handling and storage**7.1 Precautions for safe handling:**

Keep away from heat and direct sunlight.

Store in cool, dry place in tightly closed receptacles.

Prevent formation of aerosols.

Information about fire - and explosion protection: The product is not flammable.**7.2 Conditions for safe storage, including any incompatibilities:****Storage:****Requirements to be met by storerooms and receptacles:** Store only in the original receptacle.**Information about storage in one common storage facility:**

Store away from foodstuffs.

Store away from oxidising agents.

Further information about storage conditions: Store in cool, dry conditions in well sealed receptacles.**7.3 Specific end use(s):** No further relevant information available.

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SECTION 8: Exposure controls/personal protection

8.1 Control parameters:**Ingredients with limit values that require monitoring at the workplace:**

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

8.2 Exposure controls:

Appropriate engineering controls No further data; see item 7.

Individual protection measures, such as personal protective equipment**General protective and hygienic measures:**

The usual precautionary measures are to be adhered to when handling chemicals.

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing.

Wash hands before breaks and at the end of work.

Do not inhale gases / fumes / aerosols.

Avoid contact with the eyes and skin.

Respiratory protection: Not necessary if room is well-ventilated.

Hand protection Protective gloves

Material of gloves:

Butyl rubber, BR

Recommended thickness of the material: ≥ 0.7 mm

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

Penetration time of glove material:

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Eye/face protection Safety glasses

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties:**General Information:**

Colour:	Clear
Odour:	Characteristic
Odour threshold:	Not determined.
Melting point/freezing point:	Undetermined.
Boiling point or initial boiling point and boiling range	100 °C
Flammability	Not applicable.
Lower and upper explosion limit	
Lower:	Not determined.
Upper:	Not determined.
Flash point:	Not applicable.
Auto-ignition temperature:	Product is not selfigniting.
Decomposition temperature:	Not determined.
pH	3.0
Viscosity:	
Kinematic viscosity	Not determined.
Dynamic:	Not determined.
Solubility	
water:	Soluble.
Partition coefficient n-octanol/water (log value)	Not determined.
Vapour pressure:	Not determined.

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Density and/or relative density**Density:** Not determined.**Relative density:** Not determined.**Vapour density:** Not determined.**9.2 Other information:****Appearance:****Form:** Fluid**Important information on protection of health and environment, and on safety.****Explosive properties:** Product does not present an explosion hazard.**Change in condition:****Evaporation rate:** Not determined.**Information with regard to physical hazard****classes****Explosives** Void**Flammable gases** Void**Aerosols** Void**Oxidising gases** Void**Gases under pressure** Void**Flammable liquids** Void**Flammable solids** Void**Self-reactive substances and mixtures** Void**Pyrophoric liquids** Void**Pyrophoric solids** Void**Self-heating substances and mixtures** Void**Substances and mixtures, which emit flammable****gases in contact with water** Void**Oxidising liquids** Void**Oxidising solids** Void**Organic peroxides** Void**Corrosive to metals** Void**Desensitised explosives** Void**SECTION 10: Stability and reactivity****10.1 Reactivity:** No further relevant information available.**10.2 Chemical stability:****Thermal decomposition / conditions to be avoided:**

No decomposition if used according to specifications.

10.3 Possibility of hazardous reactions: No dangerous reactions known.**10.4 Conditions to avoid:** No further relevant information available.**10.5 Incompatible materials:** No further relevant information available.**10.6 Hazardous decomposition products:** No dangerous decomposition products known.**SECTION 11: Toxicological information****11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008****Acute toxicity** Based on available data, the classification criteria are not met.**Skin corrosion/irritation** Based on available data, the classification criteria are not met.**Serious eye damage/irritation** Based on available data, the classification criteria are not met.**Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.**Germ cell mutagenicity** Based on available data, the classification criteria are not met.**Carcinogenicity** Based on available data, the classification criteria are not met.

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Reproductive toxicity Based on available data, the classification criteria are not met.**STOT-single exposure** Based on available data, the classification criteria are not met.**STOT-repeated exposure** Based on available data, the classification criteria are not met.**Aspiration hazard** Based on available data, the classification criteria are not met.**11.2 Information on other hazards****Endocrine disrupting properties**

None of the ingredients is listed.

SECTION 12: Ecological information**12.1 Toxicity:****Aquatic toxicity:** No further relevant information available.**12.2 Persistence and degradability:** No further relevant information available.**12.3 Bioaccumulative potential:** No further relevant information available.**12.4 Mobility in soil:** No further relevant information available.**12.5 Results of PBT and vPvB assessment:****PBT:** Not applicable.**vPvB:** Not applicable.**12.6 Endocrine disrupting properties**

The product does not contain substances with endocrine disrupting properties.

12.7 Other adverse effects:**Additional ecological information:****General notes:**

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

SECTION 13: Disposal considerations**13.1 Waste treatment methods:****European waste catalogue:**

Dispose of contents/container in accordance with local/regional/national/international regulations.

Uncleaned packaging:**Recommendation:** Disposal must be made according to official regulations.**SECTION 14: Transport information****14.1 UN number or ID number**

ADR, ADN, IMDG, IATA

Void

14.2 UN proper shipping name:

ADR, ADN, IMDG, IATA

Void

14.3 Transport hazard class(es):

ADR, ADN, IMDG, IATA

Class:

Void

14.4 Packing group:

ADR, IMDG, IATA

Void

14.5 Environmental hazards:

Not applicable.

14.6 Special precautions for user:

Not applicable.

14.7 Maritime transport in bulk according to IMO instruments

Not applicable.

UN "Model Regulation":

Void

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SECTION 15: Regulatory information

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

Directive 2012/18/EU**Named dangerous substances - ANNEX I** None of the ingredients is listed.**DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**

None of the ingredients is listed.

15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Relevant phrases:

H302 Harmful if swallowed.

H312 Harmful in contact with skin.

H330 Fatal if inhaled.

Training hints:

Employees who use the product have to be trained on risks for health, hygiene, use of individual protection, accident preventive actions, rescue actions, etc.,

Department issuing SDS:

ADEEGO GmbH

Wildsteig 4A

D-42113 Wuppertal

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Contact: Dr. Axel Deeg**Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Acute Tox. 4: Acute toxicity - oral – Category 4

Acute Tox. 2: Acute toxicity - inhalation – Category 2