

Safety Data Sheet

According to Annex II to REACH - Regulation 2015/830

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

1.1. Product identifier

Code: 30114
Product name: Rocuronium bromide
Chemical name and synonym: 1-[(2beta,3alpha,5alpha,16beta,17beta)-17-(acetyloxy)-3-hydroxy-2-(4-morpholinyl)androstan-16-yl]-1-(2-propenyl)pyrrolidinium, bromide (9CI)
CAS number: 119302-91-9

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

Intended use: Active pharmaceutical ingredient

1.3. Details of the supplier of the safety data sheet

Name: CURIA ITALY SRL
Full address: Via del Vecchio Politecnico 9
District and Country: 20121 Milano (MI)
Italy
Tel.: +390282272
e-mail address of the competent person responsible for the Safety Data Sheet: curiaitaly@pec.it

1.4. Emergency telephone number

For urgent inquiries refer to: Rozzano Quinto De Stampi: Direzione Tecnica +39.02.822721
ValleAmbrosia: Direzione Tecnica +39.02.8228351

SECTION 2. Hazards identification

2.1. Classification of the substance or mixture

The product is classified as hazardous pursuant to the provisions set forth in (EC) Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of (EU) Regulation 2015/830.

Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

Hazard classification and indication:

Acute toxicity, category 2	H300	Fatal if swallowed.
Acute toxicity, category 1	H310	Fatal in contact with skin.
Acute toxicity, category 2	H330	Fatal if inhaled.

2.2. Label elements

Hazard labelling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms:



Signal words: Danger

Hazard statements:

H300+H310+H330 Fatal if swallowed, in contact with skin or if inhaled.

Precautionary statements:

P260 Do not breathe dust/ fume/ gas/ mist/ vapours/spray.
P262 Do not get in eyes, on skin, or on clothing.

30114 - Rocuronium bromide**SECTION 2. Hazards identification ... / >>**

P280 Wear protective gloves / clothing.
P310 Immediately call a POISON CENTER / doctor / . . .
P304+P340 IF INHALED: remove person to fresh air and keep comfortable for breathing.
P403+P233 Store in a well-ventilated place. Keep container tightly closed.

Contains: Rocuronio bromuro

CAS 119302-91-9

2.3. Other hazards

On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.

SECTION 3. Composition/information on ingredients**3.1. Substances**

C32H53N2O4 . Br.

Contains:

Identification	Conc. %	Classification 1272/2008 (CLP)
Rocuronio bromuro		
CAS 119302-91-9	100	Acute Tox. 1 H310, Acute Tox. 2 H300, Acute Tox. 2 H330
EC		
INDEX		

The full wording of hazard (H) phrases is given in section 16 of the sheet.

SECTION 4. First aid measures**4.1. Description of first aid measures**

EYES: Remove contact lenses, if present. Wash immediately with plenty of water for at least 15 minutes, opening the eyelids fully. If problem persists, seek medical advice.
SKIN: Remove contaminated clothing. Rinse skin with a shower immediately. Get medical advice/attention immediately. Wash contaminated clothing before using it again.
INHALATION: Remove to open air. If the subject stops breathing, administer artificial respiration. Get medical advice/attention immediately.
INGESTION: Get medical advice/attention immediately. Do not induce vomiting. Do not administer anything not explicitly authorised by a doctor.

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

Information not available

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

Information not available

SECTION 5. Firefighting measures**5.1. Extinguishing media**

SUITABLE EXTINGUISHING EQUIPMENT
The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray.
UNSUITABLE EXTINGUISHING EQUIPMENT
None in particular.

5.2. Special hazards arising from the substance or mixture

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE
Do not breathe combustion products. The product is combustible and, when the powder is released into the air in sufficient concentrations and in the presence of a source of ignition, it can create explosive mixtures with air. Fires may start or get worse by leakage of the solid

30114 - Rocuronium bromide**SECTION 5. Firefighting measures ... / >>**

product from the container, when it reaches high temperatures or through contact with sources of ignition.

5.3. Advice for firefighters**GENERAL INFORMATION**

Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.

SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

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

Eliminate sources of ignition (cigarettes, flames, sparks, etc.) from the air in which the leak occurred. If there are no contraindications, spray solid products with water to prevent the formation of dust. Use breathing equipment if fumes or powders are released into the air. Block the leakage if there is no hazard. Do not handle damaged containers or leaked product before donning appropriate protective gear. Send away individuals who are not suitably equipped. For information on risks for the environmental and health, respiratory tract protection, ventilation and personal protection equipment, refer to the other sections of this sheet.

6.2. Environmental precautions

The product must not penetrate the sewers, surface water, ground water and neighbouring areas.

6.3. Methods and material for containment and cleaning up

Use spark-proof mechanical equipment to collect the leaked solid product and place in plastic containers. Eliminate any residues and clean surfaces using a 5% solution of sodium hypochlorite, avoiding any dispersion: washing water must be sent to the incinerator. Air the leakage area well. Contaminated material must be disposed of in compliance with the instructions set forth in point 13.

6.4. Reference to other sections

Any information on personal protection and disposal is given in sections 8 and 13.

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

Avoid electric charge build-up. Do not smoke. Do not spray onto flames or incandescent bodies. Use in facilities fitted with suitable collection systems, in dedicated systems and under closed circuit conditions. Wear protective gloves. Use airtight safety goggles.

7.2. Conditions for safe storage, including any incompatibilities

Store in a ventilated place, in well-sealed containers, out of direct sunlight, light and moisture, at a temperature of -20°C +/- 3°C, away from all sources of combustion.
Do not use metal containers.

Storage class TRGS 510 (Germany): 6.1A

7.3. Specific end use(s)

Information not available

SECTION 8. Exposure controls/personal protection**8.1. Control parameters**

Information not available

8.2. Exposure controls**Personal protection and hygiene**

Use of adequate technical measures should always take priority over personal protective equipment. Respect general rules of hygiene such as: storing work overalls separately from normal clothes; not smoking, eating and/or drinking outside the designated areas; washing hands before eating or smoking.

Occupational exposure control

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SECTION 8. Exposure controls/personal protection ... / >>

Work with adequate localised aspiration systems. Hand protection
 Wear chemical protection gloves, in compliance with applicable EN standards.
 Eye protection
 Wear airtight goggles, in compliance with applicable EN standards.
 Skin protection
 Wear chemical protection overalls, in compliance with applicable EN standards.
 Breathing protection
 Wear facemask with P3 dust filter, in compliance with applicable EN standards.

ENVIRONMENTAL EXPOSURE CONTROLS

The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties	Value	Information
Appearance	crystalline solid	
Colour	white	
Odour	odourless	
Odour threshold	Not available	
pH	Not available	
Melting point / freezing point	Not available	
Initial boiling point	Not applicable	
Boiling range	Not available	
Flash point	Not applicable	
Evaporation Rate	Not available	
Flammability of solids and gases	Not available	
Lower inflammability limit	Not available	
Upper inflammability limit	Not available	
Lower explosive limit	Not available	
Upper explosive limit	Not available	
Vapour pressure	Not available	
Vapour density	Not available	
Relative density	Not available	
Solubility	Solubility in water at 20°C: soluble (with decomposition). Soluble in dichloromethane, ethanol, methanol and N,N-dimethylformamide.	
Partition coefficient: n-octanol/water	Not available	
Auto-ignition temperature	Not available	
Decomposition temperature	Not available	
Viscosity	Not available	
Explosive properties	Not available	
Oxidising properties	Not available	

9.2. Other information

Molecular weight	609,680
Melting range	161-169°C

SECTION 10. Stability and reactivity

10.1. Reactivity

There are no particular risks of reaction with other substances in normal conditions of use.

10.2. Chemical stability

The product is stable in normal conditions of use and storage.

10.3. Possibility of hazardous reactions

No hazardous reactions are foreseeable in normal conditions of use and storage.

10.4. Conditions to avoid

Avoid overheating, electrostatic discharge and all sources of combustion. Take all usual precautions for chemical products.

30114 - Rocuronium bromide**SECTION 10. Stability and reactivity** ... / >>**10.5. Incompatible materials**

Do not use metal containers. Exothermal reactions are possible on contact with strong oxidising or reducing agents, acids or bases.

10.6. Hazardous decomposition products

In the event of thermal decomposition or fire, may release gases and fumes that are potentially harmful to health such as carbon oxides, nitrogen oxides and hydrobromic acid.

SECTION 11. Toxicological information**11.1. Information on toxicological effects**

Man: DE50= 0,2mg/kg; DE95= 0,3mg/kg (Cooper RA et al. Can J Anaesth 1992; 39: 139-142; Engbaek J et al. Acat Anaesthesiol Scand 1994; 38: 869-878; McCluskey A et al. Anaesthesia 1997; 52: 345-349).

Mouse adult: IC50,1 (95% CL)= 22,5 (18,2-26,8) µM (Man Liu and James P. Dilger, Molecular Pharmacology; Vol 75, No 1, 166-175, 2009).

Rat adult: EC50= 9,7+/-0,7µM; Rat new born: EC50= 0,78+/-0,20µM (Fortier et al., Anesthesiology, Vol 95, No 2, 478-484, Aug 2001).

Cat: ED90= 200µg/kg (Proost et al., The Journal of Pharmacology and Experimental Therapeutics, Vol 292, No 3, 861-869, 1999).

Metabolism, toxicokinetics, mechanism of action and other information

Information not available

Information on likely routes of exposure

Information not available

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Information not available

Interactive effects

Information not available

ACUTE TOXICITY

Acute toxicity, category 1/2. Fatal if swallowed, in contact with skin or if inhaled.

SKIN CORROSION / IRRITATION

Does not meet the classification criteria for this hazard class

SERIOUS EYE DAMAGE / IRRITATION

Does not meet the classification criteria for this hazard class

RESPIRATORY OR SKIN SENSITISATION

Does not meet the classification criteria for this hazard class

GERM CELL MUTAGENICITY

Does not meet the classification criteria for this hazard class

CARCINOGENICITY

Does not meet the classification criteria for this hazard class

REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

STOT - SINGLE EXPOSURE

Does not meet the classification criteria for this hazard class

STOT - REPEATED EXPOSURE

30114 - Rocuronium bromide**SECTION 11. Toxicological information** ... / >>

Does not meet the classification criteria for this hazard class

ASPIRATION HAZARD

Does not meet the classification criteria for this hazard class

SECTION 12. Ecological information

Use this product according to good working practices. Avoid littering. Inform the competent authorities, should the product reach waterways or contaminate soil or vegetation.

12.1. Toxicity

Information not available

12.2. Persistence and degradability

Information not available

12.3. Bioaccumulative potential

Information not available

12.4. Mobility in soil

Information not available

12.5. Results of PBT and vPvB assessment

On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.

12.6. Other adverse effects

Information not available

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

Reuse, when possible. Product residues should be considered special hazardous waste. The hazard level of waste containing this product should be evaluated according to applicable regulations.

Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.

Waste transportation may be subject to ADR restrictions.

CONTAMINATED PACKAGING

Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

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

ADR / RID, IMDG, IATA: 2811

14.2. UN proper shipping name

ADR / RID: TOXIC SOLID, ORGANIC, N.O.S.

IMDG: TOXIC SOLID, ORGANIC, N.O.S.

IATA: TOXIC SOLID, ORGANIC, N.O.S.

30114 - Rocuronium bromide**SECTION 14. Transport information** ... / >>**14.3. Transport hazard class(es)**

ADR / RID: Class: 6.1 Label: 6.1



IMDG: Class: 6.1 Label: 6.1



IATA: Class: 6.1 Label: 6.1

**14.4. Packing group**

ADR / RID, IMDG, IATA: I

14.5. Environmental hazards

ADR / RID: NO

IMDG: NO

IATA: NO

14.6. Special precautions for user

ADR / RID:	HIN - Kemler: -	Limited Quantities: -	Tunnel restriction code: -
	Special Provision: -		
IMDG:	EMS: -	Limited Quantities: -	
IATA:	Cargo:	Maximum quantity: -	Packaging instructions: -
	Pass.:	Maximum quantity: -	Packaging instructions: -
	Special Instructions:	-	

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Information not relevant

SECTION 15. Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

Seveso Category - Directive 2012/18/EC: H1

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006
None

Substances in Candidate List (Art. 59 REACH)

On the basis of available data, the product does not contain any SVHC in percentage greater than 0,1%.

Substances subject to authorisation (Annex XIV REACH)

None

Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012:

None

Substances subject to the Rotterdam Convention:

None

Substances subject to the Stockholm Convention:

None

Healthcare controls

Workers exposed to this chemical agent must not undergo health checks, provided that available risk-assessment data prove that the risks related to the workers' health and safety are modest and that the 98/24/EC directive is respected.

German regulation on the classification of substances hazardous to water (AwSV, vom 18. April 2017)

WGK 3: Severe hazard to waters

Self assessment based on Annex 3

30114 - Rocuronium bromide**SECTION 15. Regulatory information ... / >>****15.2. Chemical safety assessment**

A chemical safety assessment has not been performed for the preparation/for the substances indicated in section 3.

SECTION 16. Other information

Text of hazard (H) indications mentioned in section 2-3 of the sheet:

Acute Tox. 1/2	Acute toxicity, category 1/2
Acute Tox. 1	Acute toxicity, category 1
Acute Tox. 2	Acute toxicity, category 2
H300+H310+H330	Fatal if swallowed, in contact with skin or if inhaled.
H310	Fatal in contact with skin.
H300	Fatal if swallowed.
H330	Fatal if inhaled.

LEGEND:

- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- CAS NUMBER: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE NUMBER: Identifier in ESIS (European archive of existing substances)
- CLP: EC Regulation 1272/2008
- DNEL: Derived No Effect Level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%
- IMDG: International Maritime Code for dangerous goods
- IMO: International Maritime Organization
- INDEX NUMBER: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent bioaccumulative and toxic as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PNEC: Predicted no effect concentration
- REACH: EC Regulation 1907/2006
- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA STEL: Short-term exposure limit
- TWA: Time-weighted average exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation
- WGK: Water hazard classes (German).

GENERAL BIBLIOGRAPHY

1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
3. Regulation (EU) 790/2009 (I Atp. CLP) of the European Parliament
4. Regulation (EU) 2015/830 of the European Parliament
5. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
6. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
7. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
10. Regulation (EU) 2015/1221 (VII Atp. CLP) of the European Parliament
11. Regulation (EU) 2016/918 (VIII Atp. CLP) of the European Parliament
12. Regulation (EU) 2016/1179 (IX Atp. CLP)
13. Regulation (EU) 2017/776 (X Atp. CLP)
14. Regulation (EU) 2018/669 (XI Atp. CLP)
15. Regulation (EU) 2018/1480 (XIII Atp. CLP)
16. Regulation (EU) 2019/521 (XII Atp. CLP)

- The Merck Index. - 10th Edition
- Handling Chemical Safety
- INRS - Fiche Toxicologique (toxicological sheet)

30114 - Rocuronium bromide**SECTION 16. Other information ... / >>**

- Patty - Industrial Hygiene and Toxicology- N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
- IFA GESTIS website
- ECHA website
- Database of SDS models for chemicals - Ministry of Health and ISS (Istituto Superiore di Sanità) - Italy

Note for users:

The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.

This document must not be regarded as a guarantee on any specific product property.

The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

Provide appointed staff with adequate training on how to use chemical products.

Product's classification is based on the calculation methods set out in Annex I of the CLP Regulation, unless otherwise indicated in sections 11 and 12.

The data for evaluation of chemical-physical properties are reported in section 9.

Rocuronium Bromide is employed in therapy as skeletal muscle relaxant. Provide handling places with a breath support set (oxygen, intubation cannula and AMBU).

Changes to previous review:

The following sections were modified:

01 / 09.