
1. Product Name

VECURE 10 mg, powder for injection.

2. Qualitative and Quantitative Composition

VECURE 10 mg, 1 vial contains 10 mg vecuronium bromide. When reconstituted with 5 mL water for injection corresponds to 2 mg vecuronium bromide per mL in a clear almost clear isotonic solution.

For the full list of excipients, see section 6.1

3. Pharmaceutical Form

White, freeze dried powder for injection.

Following reconstitution with solvent (water for injection) the resultant solution is isotonic and has a pH of 4.

4. Clinical Particulars

4.1 Therapeutic indications

Vecure is indicated as an adjunct to general anaesthesia to facilitate tracheal intubation and to provide skeletal muscle relaxation during surgery.

4.2 Dose and method of administration

Dosage

Like other neuromuscular blocking agents, VECURE should only be administered by, or under supervision of, experienced clinicians who are familiar with the action and use of these agents.

Like with other neuromuscular blocking agents, the dosage of VECURE should be individualised in each patient. The anaesthetic method used, the expected duration of surgery, the possible interaction with other medicines that are administered before or during anaesthesia and the condition of the patient should be taken into account when determining the dose. The use of an appropriate neuromuscular monitoring technique is recommended to monitor neuromuscular block and recovery. Inhalational anaesthetics do potentiate the neuromuscular blocking effects of VECURE. This potentiation however, becomes clinically relevant in the course of anaesthesia, when the volatile agents have reached the tissue concentrations required for this interaction. Consequently, adjustments with VECURE should be made by administering smaller maintenance doses at less frequent intervals or by using lower infusion rates of VECURE during long lasting procedures (longer than 1 hour) under inhalational anaesthesia (see section 4.5).

In adult patients the following dosage recommendations may serve as a general guideline for tracheal intubation and muscle relaxation for short to long lasting surgical procedures.

Tracheal intubation

The standard intubating dose during routine anaesthesia is 0.08 to 0.1 mg vecuronium bromide per kg body weight, after which adequate intubation conditions are established within 90 to 120 seconds in nearly all patients.

Dosages of vecuronium bromide for surgical procedures after intubation with suxamethonium

Recommended doses:

0.03 to 0.05 mg vecuronium bromide per kg body weight.

If suxamethonium is used for intubation, the administration of VECURE should be delayed until the patient has clinically recovered from the neuromuscular block induced by suxamethonium.

Maintenance dosing:

The recommended maintenance dose is 0.02 to 0.03 mg vecuronium bromide per kg body weight. These maintenance doses should best be given when twitch height has recovered to 25% of control twitch height.

Use by continuous infusion

If VECURE is administered by continuous infusion, it is recommended to give a loading dose first (see 'Tracheal intubation') and, when neuromuscular block starts to recover, to start administration of VECURE by infusion. The infusion rate should be adjusted to maintain twitch response at 10% of control twitch height or to maintain one to two responses to train of four stimulation. In adults, the infusion rate required to maintain neuromuscular block at this level, ranges from 0.8 to 1.4 microgram vecuronium bromide/kg/min. For neonates and infants, see below. Repeat monitoring of neuromuscular block is recommended since infusion rate requirements vary from patient to patient and with the anaesthetic method used.

Dosage in elderly patients

The same intubation and maintenance doses as for younger adults (0.08 to 0.1 mg/kg and 0.02 to 0.03 mg/kg, respectively) can be used. However, the duration of action is prolonged in elderly compared to younger subjects due to changes in pharmacokinetic mechanisms. The onset time in elderly is similar to younger adults.

Dosage in paediatric patients

Because of the possible variation of the sensitivity of the neuromuscular junction, especially in neonates (up to 4 weeks) and probably in infants up to 4 months of age, an initial test dose of 0.01 to 0.02 mg vecuronium bromide per kg body weight followed by incremental doses until 90 to 95% depression of twitch response is achieved is recommended. In neonatal surgery the dose should not exceed 0.1 mg/kg. Dose requirements in neonates and infants (1-12 months) are the same as in adults. However, since the onset time of vecuronium bromide in these patients is considerably shorter than in adults and children, the use of high intubating doses in general is not required for early development of good intubating conditions.

Since the duration of action and recovery time with vecuronium bromide is longer in neonates and infants than in children and adults, maintenance doses are required less frequently.

Dose requirements for children (2-10 years) are higher (see section 5.1). However, the same intubation and maintenance doses as for adults (0.08 to 0.1 mg/kg and 0.02 to 0.03 mg/kg, respectively) are usually sufficient. Since the duration of action is shorter in children, maintenance doses are required more frequently.

Although there is very little information on dosage in adolescents, it is advised to use the same dose as in adults, based on the physiological development at this age.

Dosage in overweight and obese patients

When used in overweight or obese patients (defined as patients with a body weight of 30% or more above ideal body weight), doses should be reduced taking into account an ideal body weight.

Higher doses

Should there be a reason for selection of larger doses in individual patients, initial doses ranging from 0.15 mg up to 0.30 mg vecuronium bromide per kg body weight have been administered for surgery both under halothane and neuroleptic anaesthesia without adverse cardiovascular effects being noted as long as ventilation is properly maintained. The use of these high dosages of vecuronium bromide pharmacodynamically decreases the onset time and increases the duration of action.

Administration

VECURE should be administered following reconstitution. VECURE is administered intravenously either as a bolus injection or as a continuous infusion (see also section 6).

Reconstitution

Addition of 5 mL water for injection results in an isotonic solution of pH 4 containing 2 mg vecuronium bromide per mL (2 mg/mL).

Alternatively, in order to obtain a solution with a lower concentration, VECURE may be reconstituted with a volume up to 10 mL of the following infusion fluids:

- 5% glucose injection fluid
- 0.9% sodium chloride injection fluid
- lactated Ringer's solution
- lactated Ringer's injection and 5% glucose
- glucose 5% and 0.9% sodium chloride injection.

4.3 Contraindications

Hypersensitivity to vecuronium or the bromide ion or any of the excipients of VECURE.

4.4 Special warnings and precautions for use

Since vecuronium bromide causes paralysis of the respiratory muscles, ventilatory support is mandatory for patients treated with this drug until adequate spontaneous respiration is restored.

As with other neuromuscular blocking agents, residual curarization has been reported for vecuronium bromide. In order to prevent complications resulting from residual curarization, it is recommended to extubate only after the patient has recovered sufficiently from neuromuscular block. Other factors which could cause residual curarization after extubation in the post-operative phase (such as medicine interactions or patient condition) should also be considered. If not used as part of standard clinical practice, the use of sugammadex or another reversal agent should be considered, especially in those cases where residual curarization is more likely to occur.

Anaphylactic reactions can occur following the administration of neuromuscular blocking agents. Precautions for treating such reactions should always be taken. Particularly in the case of previous anaphylactic reactions to muscle relaxants, special precautions should be taken since allergic cross-reactivity to muscle relaxants has been reported.

Since vecuronium bromide has no cardiovascular effects within the clinical dosage range, it does not attenuate bradycardia that may occur due to the use of some types of anaesthetics and opiates or due to vagal reflexes during surgery. Therefore, reassessment of the use and/or dosage of vagolytic medicines such as atropine for premedication or at induction of anaesthesia, may be of value for surgical procedures during which vagal reactions are more likely to occur (e.g. surgical

procedures where anaesthetic medicines with known vagal stimulatory effects are used, ophthalmic, abdominal or anorectal surgery, etc).

In general, following long term use of neuromuscular blocking agents in the ICU, prolonged paralysis and/or skeletal muscle weakness has been noted. In order to help preclude possible prolongation of neuromuscular block and/or overdose it is strongly recommended that neuromuscular transmission is monitored throughout the use of muscle relaxants. In addition, patients should receive adequate analgesia and sedation. Furthermore, muscle relaxants should be titrated to effect in the individual patients by or under supervision of experienced clinicians who are familiar with their actions and with appropriate neuromuscular monitoring techniques. Myopathy after long term administration of nondepolarizing neuromuscular blocking agents in the ICU in combination with corticosteroid therapy has been reported frequently. Therefore, for patients receiving both neuromuscular blocking agents and corticosteroids, the period of use of the neuromuscular blocking agent should be limited as much as possible.

The following conditions may influence the pharmacokinetics and/or pharmacodynamics of vecuronium:

Hepatic and/or biliary tract disease and renal failure

Because vecuronium bromide is excreted in bile and in urine, vecuronium bromide should be used with caution in patients with clinically significant hepatic and/or biliary diseases and/or renal failure. In these patient groups prolongation of action has been observed, especially when high doses of vecuronium (0.15 to 0.2 mg/kg bodyweight) were administered in patients with hepatic disease.

Prolonged circulation time

Conditions associated with prolonged circulation time such as cardiovascular disease, old age, oedematous state resulting in an increased volume of distribution, may contribute to an increase in the onset time of neuromuscular block. The duration of action may also be prolonged due to a reduced plasma clearance.

Neuromuscular disease

As with other neuromuscular blocking agents, vecuronium bromide should be used with extreme caution in cases of neuromuscular disease or after poliomyelitis since the response to neuromuscular blocking agents may be considerably altered in these patients. The magnitude and direction of this alteration may vary widely. In patients with myasthenia gravis or the myasthenic (Eaton Lambert) syndrome, small doses of vecuronium bromide may have profound effects and vecuronium bromide should be titrated to the response.

Hypothermia

In operations under hypothermia, the neuromuscular blocking effect of vecuronium bromide is increased and the duration is prolonged.

Obesity

Like other neuromuscular blocking agents, vecuronium bromide may exhibit a prolonged duration and a prolonged spontaneous recovery in obese patients, when the administered doses are calculated on actual body weight.

Burns

Patients with burns are known to develop resistance to non-depolarizing agents. It is recommended that the dose is titrated to response.

Conditions which may increase the effects of vecuronium bromide are hypokalaemia (e.g. after severe vomiting, diarrhoea, and diuretic therapy), hypermagnesaemia, hypocalcaemia (after massive transfusions), hypoproteinaemia, dehydration, acidosis, hypercapnoea, cachexia. Severe electrolyte disturbances, altered blood pH or dehydration should therefore be corrected when possible.

4.5 Interaction with other medicines and other forms of interaction

The following agents have been shown to influence the magnitude and/or duration of action of non-depolarising neuromuscular blocking agents.

Effect of other agents on vecuronium bromide

Increased effect

Halogenated volatile anaesthetics potentiate the neuromuscular block of vecuronium bromide. The effect only becomes apparent with maintenance dosing (see section 4.2). Reversal of the block with anticholinesterase inhibitors could also be inhibited.

After intubation with suxamethonium (see section 4.2).

Long-term concomitant use of corticosteroids and vecuronium bromide in the ICU may result in prolonged duration of neuromuscular block or myopathy (see section 4.4 and 4.8).

Other medicines,

- Antibiotics: aminoglycoside, lincosamide and polypeptide antibiotics, acylamino-penicillin antibiotics.
- Diuretics, quinidine, magnesium salts, calcium channel blocking agents, lithium salts, cimetidine, lidocaine and acute administration of phenytoin or beta-blocking agents.
- Recurarisation has been reported after post-operative administration of aminoglycoside, lincosamide, polypeptide and acylamino-penicillin antibiotics, quinidine and magnesium salts (see section 4.4).

Decreased effect (possible higher dose requirements)

Prior chronic administration of phenytoin or carbamazepine.

Variable effect

Administration of other non-depolarising neuromuscular blocking agents in combination with vecuronium bromide may produce attenuation or potentiation of the neuromuscular block, depending on the order of administration and the neuromuscular blocking agent used.

Suxamethonium given after the administration of vecuronium bromide may produce potentiation or attenuation of the neuromuscular blocking effect of vecuronium bromide.

Effect of vecuronium bromide on other drugs

Vecuronium bromide combined with lidocaine may result in a quicker onset of action of lidocaine.

4.6 Fertility, pregnancy and lactation

Use in pregnancy

There are insufficient data on the use of vecuronium bromide during animal or human pregnancy to assess potential harm to the foetus. Vecuronium bromide should be given to a pregnant woman only when the attending physician decides that the benefits outweigh the risks.

Caesarean section

Studies with vecuronium bromide, administered in doses up to 0.1 mg/kg, have shown its safety for use in caesarean section. In caesarean section the dose should not exceed 0.1 mg/kg. In several clinical studies vecuronium bromide did not affect Apgar score, foetal muscle tonus or cardiorespiratory adaptation.

From umbilical cord blood sampling it is apparent that only very little placental transfer of vecuronium bromide occurs which did not lead to the observation of any clinical adverse effect in the newborn.

Note: Reversal of a vecuronium-induced neuromuscular block may be inhibited or unsatisfactory in patients receiving magnesium sulphate for toxæmia of pregnancy because magnesium salts enhance neuromuscular block. Therefore, in patients receiving magnesium sulphate, the dosage of vecuronium bromide should be reduced and be carefully titrated to twitch response.

Use in lactation

There are no human data on the use of vecuronium bromide during lactation. Vecuronium bromide should be given to lactating women only when the attending physician decides that the benefits outweigh the risks.

4.7 Effects on ability to drive and use machines

Since vecuronium bromide is used as an adjunct to general anaesthesia, the usual precautionary measures after general anaesthesia should be taken for ambulatory patients.

4.8 Undesirable effects

Adverse drug reactions (ADRs) are rare (<1/1,000). The most commonly occurring ADRs include changes in vital signs and prolonged neuromuscular block. The most frequently reported ADR during post-marketing surveillance is 'anaphylactic and anaphylactoid reactions' and associated symptoms (reporting frequency <1/100,000).

MedDRA SOC	Preferred term ¹	
	Uncommon/rare (<1/100, >1/10,000)	Very rare (<1/10,000)
Immune system disorders		Hypersensitivity Anaphylactic reaction Anaphylactoid reaction Anaphylactic shock Anaphylactoid shock
Nervous system disorders		Flaccid paralysis
Cardiac disorders	Tachycardia	
Vascular disorders	Hypotension	Circulatory collapse and shock Flushing
Respiratory, thoracic and mediastinal disorders		Bronchospasm
Skin and subcutaneous tissue disorders		Angioneurotic oedema Urticaria Rash Erythematous rash
Musculoskeletal and connective tissue disorders		Muscular weakness ² Steroid myopathy ²
General disorders and administration site conditions	Drug ineffective Decreased drug effect/therapeutic response Increased drug effect/therapeutic response	Face oedema Injection site pain Injection site reactions

Injury, poisoning and procedural complications	Prolonged neuromuscular block Delayed recovery from anaesthesia	Airway complication of anaesthesia
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¹ Frequencies are estimates derived from post-marketing surveillance reports and data from the general literature

² After long-term use in the ICU

Prolonged neuromuscular block

The most frequent adverse reactions to non-depolarising blocking agents as a class consist of an extension of the pharmacological action beyond the time period needed. This may vary from skeletal muscle weakness to profound and prolonged skeletal muscle paralysis resulting in respiratory insufficiency or apnoea. A few cases of myopathy have been reported after vecuronium bromide was used in the ICU in combination with corticosteroids (see section 4.4).

Anaphylactic reactions

Although very rare, severe anaphylactic reactions to neuromuscular blocking agents, including vecuronium bromide, have been reported. Anaphylactic/anaphylactoid reactions usually comprise of several signs or symptoms, e.g. bronchospasm, cardiovascular changes (e.g. hypotension, tachycardia, circulatory collapse - shock) and cutaneous changes (e.g. angioedema, urticaria). These reactions have, in some cases, been fatal. Due to the possible severity of these reactions, one should always assume they may occur and take the necessary precautions.

Histamine release and histaminoid reactions

Since neuromuscular blocking agents are known to be capable of inducing histamine release both locally at the site of injection and systemically, the possible occurrence of itching and erythematous reactions at the site of injection and/or generalised histaminoid (anaphylactoid) reactions should always be taken into consideration when administering these agents (see also 'Anaphylactic reaction' above).

Experimental studies with intradermal injection of vecuronium bromide have demonstrated that this medicine has only a weak capacity for inducing local histamine release.

Controlled studies in humans failed to demonstrate any significant rise in plasma histamine levels after intravenous administration of vecuronium bromide. Still, such cases have rarely been reported during large scale use of vecuronium bromide.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions <https://nzphvc.otago.ac.nz/reporting/>.

4.9 Overdose

In the event of overdosage and prolonged neuromuscular block, the patient should continue to receive ventilatory support and sedation. In this situation there are two options for the reversal of neuromuscular block:

- (1) Sugammadex can be used for reversal of intense (profound) and deep block. The dose of sugammadex to be administered depends on the level of neuromuscular block.
- (2) An acetylcholinesterase inhibitor (e.g. neostigmine, edrophonium, pyridostigmine) can be used at reappearance of T₂ or at the first signs of clinical recovery and should be administered in adequate doses.

When administration of an acetylcholinesterase-inhibiting agent fails to reverse the neuromuscular effects of vecuronium bromide, ventilation must be continued until spontaneous breathing is restored.

Repeated dosage of an acetylcholinesterase inhibitor can be dangerous.

For further advice on management of overdose please contact the National Poisons Information Centre (0800 POISON or 0800 764 766).

5. Pharmacological Properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: muscle relaxants, peripherally acting agents, ATC code: MO3A C03.

Vecuronium bromide is a non-depolarising neuromuscular blocking agent, chemically designated as the aminosteroid 1-(3 α , 17 β -diacetoxy-2 β piperidino-5 α -androstan-16 β -yl)-1 methylpiperidinium bromide. Vecuronium bromide blocks the transmission process between the motor nerve-ending and striated muscle by binding competitively with acetylcholine to the nicotinic receptors located in the motor end-plate region of striated muscle.

Unlike depolarising neuromuscular blocking agents, such as suxamethonium, vecuronium bromide does not cause muscle fasciculations.

Within the clinical dosage range, vecuronium bromide exerts no vagolytic nor ganglion blocking activity.

Tracheal intubation

Within 90 to 120 seconds following intravenous administration of a dose of 0.08 to 0.10 mg vecuronium bromide per kg body weight, good to excellent conditions for tracheal intubation occur and within 3 to 4 minutes following administration of these dosages, general muscle paralysis adequate for any type of surgery is established.

The duration of action to 25% recovery of control twitch height (clinical duration) with this dose is 24 to 60 minutes. The time to 95% recovery of control twitch height following this dose is approximately 60 to 80 minutes.

With higher dosages of vecuronium bromide, onset time to maximal block is shortened and duration of action is prolonged.

Continuous intravenous infusion

In case vecuronium bromide is administered by continuous intravenous infusion, a steady state neuromuscular blockade of 90% can be maintained at a constant rate of delivery and without clinically significant prolongation of the recovery time from neuromuscular block at termination of the infusion.

Vecuronium bromide has no cumulative effects if maintenance doses are administered at 25% recovery of control twitch height. Several maintenance doses can therefore be given in succession. The abovementioned properties mean that vecuronium bromide can be used equally as well in short, as in long lasting surgical procedures.

Reversal of neuromuscular block

The action of vecuronium can be antagonized either by sugammadex or by acetylcholinesterase inhibitors, such as neostigmine, pyridostigmine or edrophonium. Sugammadex can be given for routine reversal at 1-2 post-tetanic counts to reappearance of T₂. Acetylcholinesterase inhibitors can be administered at reappearance of T₂ or at the first signs of clinical recovery.

Use in paediatric patients

Neonates and infants

In neonates and infants the ED₉₅ dose of vecuronium bromide under nitrous oxide in oxygen anaesthesia was found to be approximately the same (approximately 47 microgram/kg body weight) as in adults. The onset time of vecuronium bromide in neonates and infants is considerably shorter as compared to children and adults, probably due to the shorter circulation time and relatively large cardiac output. Also, greater sensitivity of the neuromuscular junction to the action of neuromuscular blocking agents in these patients may account for a more rapid onset of action.

The duration of action and recovery time with vecuronium bromide is longer in neonates and infants than in adults. Maintenance doses of vecuronium bromide should, therefore, be less frequently administered.

Children

In children the ED₉₅ dose of vecuronium bromide under nitrous oxide in oxygen anaesthesia was found to be higher than in adults (0.081 versus 0.043 mg/kg body weight, respectively). In comparison to adults, the duration of action and recovery time with vecuronium bromide in children are in general approximately 30% and 20% to 30% shorter, respectively.

Similar to adults, cumulative effects with repeat maintenance doses of approximately one-quarter of the initial dose and administered at 25% recovery of control twitch height are not observed in paediatric patients.

5.2 Pharmacokinetic properties

After intravenous administration of 0.1 to 0.15 mg/kg vecuronium, the distribution half-life of vecuronium amounts to 1.2 to 1.4 minutes. Vecuronium is mainly distributed in the extracellular fluid compartment. At steady state, the volume of distribution is 0.19 to 0.51 L/kg in adult patients.

The plasma clearance of vecuronium amounts to 3.0 to 6.4 mL/kg/min and its plasma elimination half-life is 36 to 117 minutes.

The extent of metabolism of vecuronium is relatively low. In humans, a 3-hydroxy derivative having approximately 50% less neuromuscular blocking potency than vecuronium is formed in the liver. In patients not suffering from renal or hepatic failure, the plasma concentration of this derivative is below the limit of detection, and does not contribute to the neuromuscular block occurring after administration of vecuronium bromide.

Biliary excretion is the main elimination route. It is estimated that within 24 hours after intravenous administration of vecuronium bromide, 40 to 60% of the dose administered is excreted into the bile as monoquaternary compounds. Approximately 95% of these monoquaternary compounds is unchanged vecuronium and less than 5% is 3-hydroxy vecuronium. Prolonged duration of action has been observed in patients with liver disease and/or biliary tract disease, probably as a result of decreased clearance leading to an increased elimination half-life.

Renal elimination is relatively low. The amount of monoquaternary compounds excreted in the urine collected by intravesical catheter for 24 hours following vecuronium bromide administration is 20 to 30% of the dose administered. In patients with renal failure, the duration of action may be prolonged. This is probably the result of an increased sensitivity to vecuronium, but it could also be the result of a reduced plasma clearance.

5.3 Preclinical safety data

Vecuronium bromide showed no genotoxic, embryotoxic or teratogenic potential. Single and repeated dose toxicity studies in rats, dogs and cats revealed no special hazard for humans.

6. Pharmaceutical Particulars

6.1 List of excipients

VECURE 10 mg vial also contains: Anhydrous citric acid 20.75 mg, dibasic anhydrous sodium phosphate 16.25 mg, mannitol 97 mg, sodium hydroxide and phosphoric acid q.s for pH adjustment.

6.2 Incompatibilities

As is the case for many other drugs, vecuronium bromide has been shown to be **incompatible** when added to thiopentone or solutions containing thiopentone.

Compatibility studies with other brands of these drugs or with other infusion fluids have not been performed.

If VECURE is administered via the same infusion line that is also used for other drugs, it is important that this infusion line is adequately flushed (e.g. with NaCl 0.9%) between administration of vecuronium bromide and drugs for which incompatibility with vecuronium bromide has been demonstrated or for which compatibility with vecuronium bromide has not been established.

6.3 Shelf life

2 years.

To avoid microbial contamination, VECURE should be used without delay once reconstituted and any residue should be discarded.

6.4 Special precautions for storage

Stored at or below 25°C and protected from light.

6.5 Nature and contents of container

10 mL vials each containing 10.0 mg sterile lyophilised vecuronium bromide powder for reconstitution, in boxes of 10 vials.

6.6 Special precautions for disposal and other handling

Compatibilities with infusions

When VECURE is reconstituted with water for injections, the resultant solution can be mixed with the following infusion fluids, packed in PVC or glass, to a dilution up to 40 mg/L:

- sodium chloride 0.9% solution
- glucose 5% solution
- Ringer's solution
- Ringer's glucose.

When reconstituted with water for injections, VECURE can also be injected into the line of a running infusion of the following fluids:

- lactated Ringer's solution
- lactated Ringer's solution and glucose 5%
- glucose 5% and sodium chloride 0.9% solution
- Haemaccel
- Dextran-40 5% in sodium chloride 0.9% solution.

Neither the reconstituted VECURE in water for injections nor the solutions further diluted with the compatible infusion fluids contain any antimicrobial preservatives. To avoid microbial

contamination hazards, the reconstituted or further diluted VECURE injections should be used immediately after preparation and any residue discarded. Do not use VECURE when the solution after reconstitution contains particles or is not clear.

7. Medicines Schedule

Prescription Medicine

8. Sponsor Details

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9. Date of First Approval

22 February 2018

10. Date of Revision of the Text

22 February 2018 New data sheet
