

SCHEDULE 1

Regulation 3

Form of provisional authorisation of cobalt(II) acetate tetrahydrate (identification number 3b301) as a feed additive for ruminants with a functional rumen, equidae, lagomorphs, rodents, herbivore reptiles and zoo mammals

The substance cobalt(II) acetate tetrahydrate, belonging to the additive category 'nutritional additives' and to the functional group 'compounds of trace elements', is provisionally authorised as an additive in animal nutrition in accordance with the specifications in the following table.

<i>Additive</i>	Cobalt(II) acetate tetrahydrate	
<i>Identification number of the additive</i>	3b301	
<i>Authorisation holder⁽¹⁾</i>		
<i>Additive category</i>	Nutritional additives	
<i>Functional group</i>	Compounds of trace elements	
<i>Additive composition</i>	Cobalt(II) acetate tetrahydrate Crystals or granules containing a minimum content of 23% cobalt Particles < 50 µm: below 1%	
<i>Characterisation of the active substance(s)</i>	Chemical formula: $\text{Co}(\text{CH}_3\text{COO})_2 \times 4\text{H}_2\text{O}$ CAS number: 6147-53-1 ⁽²⁾	
<i>Analytical methods⁽³⁾</i>	For the identification of acetate in the additive: • European Pharmacopoeia monograph 20301 ⁽⁴⁾	
	For the crystallographic characterisation of the additive: • X-Ray diffraction	
	For the determination of total cobalt in the additive, premixtures, feed materials and compound feed: • Inductively coupled plasma optical (atomic) emission spectrometry (ICP-AES) in accordance with BS EN 15510:2017 ⁽⁵⁾ ; or • Inductively coupled plasma optical (atomic) emission spectrometry (ICP-AES) after pressure digestion in accordance with BS EN 15621:2017 ⁽⁶⁾	
	For the determination of particle size distribution: • Particle size analysis, laser diffraction methods in accordance with BS ISO 13320:2020 ⁽⁷⁾	
<i>Species or category of animal</i>	Ruminants with a functional rumen, equidae, lagomorphs, rodents, herbivore reptiles and zoo mammals	
<i>Maximum age</i>	Not applicable	
<i>Element (Co) in mg/kg of complete feed with</i>	<i>Minimum content</i>	No minimum

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

<i>Additive</i>		Cobalt(II) acetate tetrahydrate
<i>a moisture content of 12%</i>	<i>Maximum content</i>	1 (total)
<i>Other provisions</i>		<p>1) The additive must be incorporated into compound feed in the form of a premixture</p> <p>2) The following must be stated on the labelling of the additive and premixture:</p> <ul style="list-style-type: none"> • The element (cobalt) content • “It is recommended to limit the supplementation with cobalt to 0.3 mg/kg in complete feed. In this context, the risk for cobalt deficiency due to local conditions and the specific composition of the diet should be taken into account” <p>3) The following must be stated in the instructions for use of the compound feed:</p> <ul style="list-style-type: none"> • “Protective measures to avoid exposure with cobalt by inhalation or by dermal route should be taken”
<i>Start of provisional authorisation period</i>		15 July 2023
<i>End of provisional authorisation period</i>		14 July 2028

- (1) There is no requirement to include the name of the holder of this authorisation as this authorisation does not fall within the scope of Article 9(5) of Regulation (EC) 1831/2003.
- (2) This is a reference to the CAS Registry Number[®] assigned to this substance by the Chemical Abstracts Service <https://cas.org/cas-data/cas-registry>.
- (3) Details of the analytical methods are set out in the document referenced “JRC.D.5/FSQ/CvH/PRO/ag/Ares(2012)214390” and last updated on 6th June 2016. This document is available at the following address: https://joint-research-centre.ec.europa.eu/publications/fad-cobalt-group_en.
- (4) “Monograph 20301: 2.3.1. Identification reactions of ions and functional groups”. European Pharmacopoeia, European Directorate for the Quality of Medicines and Healthcare 11th edition. Published July 2022 (ISBN 978 92 871 9105 2). Available from European Pharmacopoeia Online <https://pheur.edqm.eu/home>.
- (5) BS EN 15510:2017 “Animal feeding stuffs. Methods of sampling and analysis. Determination of calcium, sodium, phosphorus, magnesium, potassium, iron, zinc, copper, manganese, cobalt, molybdenum and lead by ICP-AES”. Published by the British Standards Institution on 31st August 2017 (ISBN 978 0 580 94541 0). Available from the British Standards Institution <https://knowledge.bsigroup.com>.
- (6) BS EN 15621:2017 “Animal feeding stuffs: Methods of sampling and analysis. Determination of calcium, sodium, phosphorus, magnesium, potassium, sulphur, iron, zinc, copper, manganese and cobalt after pressure digestion by ICP-AES”. Published by the British Standards Institution on 31st August 2017 (ISBN 978 0 580 94543 4). Available from the British Standards Institution <https://knowledge.bsigroup.com>.
- (7) BS ISO 13320:2020 “Particle size analysis. Laser diffraction methods”. Published by the British Standards Institution on 31st July 2020 (ISBN 978 0 580 92329 6). Available from the British Standards Institution <https://knowledge.bsigroup.com>.

SCHEDULE 2

Regulation 3

Form of provisional authorisation of cobalt(II) carbonate (identification number 3b302) as a feed additive for ruminants with a functional rumen, equidae, lagomorphs, rodents, herbivore reptiles and zoo mammals

The substance cobalt(II) carbonate, belonging to the additive category 'nutritional additives' and to the functional group 'compounds of trace elements', is provisionally authorised as an additive in animal nutrition in accordance with the specifications in the following table.

<i>Additive</i>	Cobalt(II) carbonate
<i>Identification number of the additive</i>	3b302
<i>Authorisation holder⁽¹⁾</i>	
<i>Additive category</i>	Nutritional additives
<i>Functional group</i>	Compounds of trace elements
<i>Additive composition</i>	<p>Cobalt(II) carbonate</p> <p>Powder containing a minimum content of 46% cobalt</p> <p>Cobalt carbonate: minimum 75%</p> <p>Cobalt hydroxide: 3% - 15%</p> <p>Water: maximum 6%</p> <p>Particles < 11 µm: below 90%</p>
<i>Characterisation of the active substance(s)</i>	<p>Chemical formula: CoCO_3</p> <p>CAS number: 513-79-1⁽²⁾</p>
<i>Analytical methods⁽³⁾</i>	<p>For the identification of carbonate in the additive:</p> <ul style="list-style-type: none"> • European Pharmacopoeia monograph 20301⁽⁴⁾ <p>For the crystallographic characterisation of the additive:</p> <ul style="list-style-type: none"> • X-Ray diffraction <p>For the determination of total cobalt in the additive, premixtures, feed materials and compound feed:</p> <ul style="list-style-type: none"> • Inductively coupled plasma optical (atomic) emission spectrometry (ICP-AES) in accordance with BS EN 15510:2017⁽⁵⁾; or • Inductively coupled plasma optical (atomic) emission spectrometry (ICP-AES) after pressure digestion in accordance with BS EN 15621:2017⁽⁶⁾ <p>For the determination of particle size distribution:</p> <ul style="list-style-type: none"> • Particle size analysis, laser diffraction methods in accordance with BS ISO 13320:2020⁽⁷⁾
<i>Species or category of animal</i>	Ruminants with a functional rumen, equidae, lagomorphs, rodents, herbivore reptiles and zoo mammals

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

<i>Additive</i>		Cobalt(II) carbonate
<i>Maximum age</i>		Not applicable
<i>Element (Co) in mg/kg of complete feed with a moisture content of 12%</i>	<i>Minimum content</i>	No minimum
	<i>Maximum content</i>	1 (total)
<i>Other provisions</i>		<ol style="list-style-type: none"> 1) The additive must be incorporated into compound feed in the form of a premixture. This compound feed must be placed on the market in a non-powdered form 2) The following must be stated on the labelling of the additive and premixture: <ul style="list-style-type: none"> • The element (cobalt) content • “It is recommended to limit the supplementation with cobalt to 0.3 mg/kg in complete feed. In this context, the risk for cobalt deficiency due to local conditions and the specific composition of the diet should be taken into account” 3) The following must be stated in the instructions for use of the compound feed: <ul style="list-style-type: none"> • “Protective measures to avoid exposure with cobalt by inhalation or by dermal route should be taken”
<i>Start of provisional authorisation period</i>		15 July 2023
<i>End of provisional authorisation period</i>		14 July 2028

- (1) There is no requirement to include the name of the holder of this authorisation as this authorisation does not fall within the scope of Article 9(5) of Regulation (EC) 1831/2003.
- (2) This is a reference to the CAS Registry Number[®] assigned to this substance by the Chemical Abstracts Service <https://cas.org/cas-data/cas-registry>.
- (3) Details of the analytical methods are set out in the document referenced “JRC.D.5/FSQ/CvH/PRO/ag/Ares(2012)214390” and last updated on 6th June 2016. This document is available at the following address: https://joint-research-centre.ec.europa.eu/publications/fad-cobalt-group_en.
- (4) “Monograph 20301: 2.3.1. Identification reactions of ions and functional groups”. European Pharmacopoeia, European Directorate for the Quality of Medicines and Healthcare 11th edition. Published July 2022 (ISBN 978 92 871 9105 2). Available from European Pharmacopoeia Online <https://pheur.edqm.eu/home>.
- (5) BS EN 15510:2017 “Animal feeding stuffs. Methods of sampling and analysis. Determination of calcium, sodium, phosphorus, magnesium, potassium, iron, zinc, copper, manganese, cobalt, molybdenum and lead by ICP-AES”. Published by the British Standards Institution on 31st August 2017 (ISBN 978 0 580 94541 0). Available from the British Standards Institution <https://knowledge.bsigroup.com>.
- (6) BS EN 15621:2017 “Animal feeding stuffs: Methods of sampling and analysis. Determination of calcium, sodium, phosphorus, magnesium, potassium, sulphur, iron, zinc, copper, manganese and cobalt after pressure digestion by ICP-AES”. Published by the British Standards Institution on 31st August 2017 (ISBN 978 0 580 94543 4). Available from the British Standards Institution <https://knowledge.bsigroup.com>.
- (7) BS ISO 13320:2020 “Particle size analysis. Laser diffraction methods”. Published by the British Standards Institution on 31st July 2020 (ISBN 978 0 580 92329 6). Available from the British Standards Institution <https://knowledge.bsigroup.com>.

SCHEDULE 3

Regulation 3

Form of provisional authorisation of cobalt(II) carbonate hydroxide (2:3) monohydrate (identification number 3b303) as a feed additive for ruminants with a functional rumen, equidae, lagomorphs, rodents, herbivore reptiles and zoo mammals

The substance cobalt(II) carbonate hydroxide (2:3) monohydrate, belonging to the additive category 'nutritional additives' and to the functional group 'compounds of trace elements', is provisionally authorised as an additive in animal nutrition in accordance with the specifications in the following table.

<i>Additive</i>	Cobalt(II) carbonate hydroxide (2:3) monohydrate	
<i>Identification number of the additive</i>	3b303	
<i>Authorisation holder⁽¹⁾</i>		
<i>Additive category</i>	Nutritional additives	
<i>Functional group</i>	Compounds of trace elements	
<i>Additive composition</i>	Cobalt(II) carbonate hydroxide (2:3) monohydrate Powder with a minimum content of 50% cobalt Particles < 50 µm: below 98%	
<i>Characterisation of the active substance(s)</i>	Chemical formula: $2\text{CoCO}_3 \times 3\text{Co}(\text{OH})_2 \times \text{H}_2\text{O}$ CAS number: 51839-24-8 ⁽²⁾	
<i>Analytical methods⁽³⁾</i>	For the identification of carbonate in the additive: <ul style="list-style-type: none"> • European Pharmacopoeia monograph 20301⁽⁴⁾ 	
	For the crystallographic characterisation of the additive: <ul style="list-style-type: none"> • X-Ray diffraction 	
	For the determination of total cobalt in the additive, premixtures, feed materials and compound feed: <ul style="list-style-type: none"> • Inductively coupled plasma optical (atomic) emission spectrometry (ICP-AES) in accordance with BS EN 15510:2017⁽⁵⁾; or • Inductively coupled plasma optical (atomic) emission spectrometry (ICP-AES) after pressure digestion in accordance with BS EN 15621:2017⁽⁶⁾ 	
	For the determination of particle size distribution: <ul style="list-style-type: none"> • Particle size analysis, laser diffraction methods in accordance with BS ISO 13320:2020⁽⁷⁾ 	
<i>Species or category of animal</i>	Ruminants with a functional rumen, equidae, lagomorphs, rodents, herbivore reptiles and zoo mammals	
<i>Maximum age</i>	Not applicable	
<i>Element (Co) in mg/kg of complete</i>	<i>Minimum content</i>	No minimum

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

<i>Additive</i>	Cobalt(II) carbonate hydroxide (2:3) monohydrate	
<i>feed with a moisture content of 12%</i>	<i>Maximum content</i>	1 (total)
<i>Other provisions</i>	<p>1) The additive must be incorporated into compound feed in the form of a premixture. This compound feed must be placed on the market in a non-powdered form</p> <p>2) The following must be stated on the labelling of the additive and premixture:</p> <ul style="list-style-type: none"> • The element (cobalt) content • “It is recommended to limit the supplementation with cobalt to 0.3 mg/kg in complete feed. In this context, the risk for cobalt deficiency due to local conditions and the specific composition of the diet should be taken into account” <p>3) The following must be stated in the instructions for use of the compound feed:</p> <ul style="list-style-type: none"> • “Protective measures to avoid exposure with cobalt by inhalation or by dermal route should be taken” 	
<i>Start of provisional authorisation period</i>	15 July 2023	
<i>End of provisional authorisation period</i>	14 July 2028	

- (1) There is no requirement to include the name of the holder of this authorisation as this authorisation does not fall within the scope of Article 9(5) of Regulation (EC) 1831/2003.
- (2) This is a reference to the CAS Registry Number[®] assigned to this substance by the Chemical Abstracts Service <https://cas.org/cas-data/cas-registry>.
- (3) Details of the analytical methods are set out in the document referenced “JRC.D.5/FSQ/CvH/PRO/ag/Ares(2012)214390” and last updated on 6th June 2016. This document is available at the following address: https://joint-research-centre.ec.europa.eu/publications/fad-cobalt-group_en.
- (4) “Monograph 20301: 2.3.1. Identification reactions of ions and functional groups”. European Pharmacopoeia, European Directorate for the Quality of Medicines and Healthcare 11th edition. Published July 2022 (ISBN 978 92 871 9105 2). Available from European Pharmacopoeia Online <https://pheur.edqm.eu/home>.
- (5) BS EN 15510:2017 “Animal feeding stuffs. Methods of sampling and analysis. Determination of calcium, sodium, phosphorus, magnesium, potassium, iron, zinc, copper, manganese, cobalt, molybdenum and lead by ICP-AES”. Published by the British Standards Institution on 31st August 2017 (ISBN 978 0 580 94541 0). Available from the British Standards Institution <https://knowledge.bsigroup.com>.
- (6) BS EN 15621:2017 “Animal feeding stuffs: Methods of sampling and analysis. Determination of calcium, sodium, phosphorus, magnesium, potassium, sulphur, iron, zinc, copper, manganese and cobalt after pressure digestion by ICP-AES”. Published by the British Standards Institution on 31st August 2017 (ISBN 978 0 580 94543 4). Available from the British Standards Institution <https://knowledge.bsigroup.com>.
- (7) BS ISO 13320:2020 “Particle size analysis. Laser diffraction methods”. Published by the British Standards Institution on 31st July 2020 (ISBN 978 0 580 92329 6). Available from the British Standards Institution <https://knowledge.bsigroup.com>.

SCHEDULE 4

Regulation 3

Form of provisional authorisation of cobalt(II) sulphate heptahydrate (identification number 3b305) as a feed additive for ruminants with a functional rumen, equidae, lagomorphs, rodents, herbivore reptiles and zoo mammals

The substance cobalt(II) sulphate heptahydrate, belonging to the additive category 'nutritional additives' and to the functional group 'compounds of trace elements', is provisionally authorised as an additive in animal nutrition in accordance with the specifications in the following table.

<i>Additive</i>	Cobalt(II) sulphate heptahydrate	
<i>Identification number of the additive</i>	3b305	
<i>Authorisation holder⁽¹⁾</i>		
<i>Additive category</i>	Nutritional additives	
<i>Functional group</i>	Compounds of trace elements	
<i>Additive composition</i>	Cobalt(II) sulphate heptahydrate Powder with a minimum content of 20% cobalt Particles < 50 µm: below 95%	
<i>Characterisation of the active substance(s)</i>	Chemical formula: $\text{CoSO}_4 \times 7\text{H}_2\text{O}$ CAS number: 10026-24-1 ⁽²⁾	
<i>Analytical methods⁽³⁾</i>	For the identification of sulphate in the additive: <ul style="list-style-type: none"> • European Pharmacopoeia monograph 20301⁽⁴⁾ 	
	For the crystallographic characterisation of the additive: <ul style="list-style-type: none"> • X-Ray diffraction 	
	For the determination of total cobalt in the additive, premixtures, feed materials and compound feed: <ul style="list-style-type: none"> • Inductively coupled plasma optical (atomic) emission spectrometry (ICP-AES) in accordance with BS EN 15510:2017⁽⁵⁾; or • Inductively coupled plasma optical (atomic) emission spectrometry (ICP-AES) after pressure digestion in accordance with BS EN 15621:2017⁽⁶⁾ 	
	For the determination of particle size distribution: <ul style="list-style-type: none"> • Particle size analysis, laser diffraction methods in accordance with BS ISO 13320:2020⁽⁷⁾ 	
<i>Species or category of animal</i>	Ruminants with a functional rumen, equidae, lagomorphs, rodents, herbivore reptiles and zoo mammals	
<i>Maximum age</i>	Not applicable	
<i>Element (Co) in mg/kg of complete feed with</i>	<i>Minimum content</i>	No minimum

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

<i>Additive</i>		Cobalt(II) sulphate heptahydrate
<i>a moisture content of 12%</i>	<i>Maximum content</i>	1 (total)
<i>Other provisions</i>		<p>1) The additive must be incorporated into compound feed in the form of a premixture. This compound feed must be placed on the market in a non-powdered form</p> <p>2) The following must be stated on the labelling of the additive and premixture:</p> <ul style="list-style-type: none"> • The element (cobalt) content • “It is recommended to limit the supplementation with cobalt to 0.3 mg/kg in complete feed. In this context, the risk for cobalt deficiency due to local conditions and the specific composition of the diet should be taken into account” <p>3) The following must be stated in the instructions for use of the compound feed:</p> <ul style="list-style-type: none"> • “Protective measures to avoid exposure with cobalt by inhalation or by dermal route should be taken”
<i>Start of provisional authorisation period</i>		15 July 2023
<i>End of provisional authorisation period</i>		14 July 2028

- (1) There is no requirement to include the name of the holder of this authorisation as this authorisation does not fall within the scope of Article 9(5) of Regulation (EC) 1831/2003.
- (2) This is a reference to the CAS Registry Number[®] assigned to this substance by the Chemical Abstracts Service <https://cas.org/cas-data/cas-registry>.
- (3) Details of the analytical methods are set out in the document referenced “JRC.D.5/FSQ/CvH/PRO/ag/Ares(2012)214390” and last updated on 6th June 2016. This document is available at the following address: https://joint-research-centre.ec.europa.eu/publications/fad-cobalt-group_en.
- (4) “Monograph 20301: 2.3.1. Identification reactions of ions and functional groups”. European Pharmacopoeia, European Directorate for the Quality of Medicines and Healthcare 11th edition. Published July 2022 (ISBN 978 92 871 9105 2). Available from European Pharmacopoeia Online <https://pheur.edqm.eu/home>.
- (5) BS EN 15510:2017 “Animal feeding stuffs. Methods of sampling and analysis. Determination of calcium, sodium, phosphorus, magnesium, potassium, iron, zinc, copper, manganese, cobalt, molybdenum and lead by ICP-AES”. Published by the British Standards Institution on 31st August 2017 (ISBN 978 0 580 94541 0). Available from the British Standards Institution <https://knowledge.bsigroup.com>.
- (6) BS EN 15621:2017 “Animal feeding stuffs: Methods of sampling and analysis. Determination of calcium, sodium, phosphorus, magnesium, potassium, sulphur, iron, zinc, copper, manganese and cobalt after pressure digestion by ICP-AES”. Published by the British Standards Institution on 31st August 2017 (ISBN 978 0 580 94543 4). Available from the British Standards Institution <https://knowledge.bsigroup.com>.
- (7) BS ISO 13320:2020 “Particle size analysis. Laser diffraction methods”. Published by the British Standards Institution on 31st July 2020 (ISBN 978 0 580 92329 6). Available from the British Standards Institution <https://knowledge.bsigroup.com>.