SCHEDULE 1 Regulation 3(1)

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, subject to the conditions set out in the table.

Column 1	*Column 2*
Additive	Cobalt(II) acetate tetrahydrate
Identification number of the additive	3b301
Authorisation holder[(1)]	
Additive category	Nutritional additives
Functional group	Compounds of trace elements
Additive composition	Cobalt(II) acetate tetrahydrate, as crystals/granules, with a minimum content of 23% cobalt Particles < 50 μm: below 1%
Characterisation of the active substance(s)	Chemical formula: $Co(CH_3COO)_2 \times 4H_2O$ CAS number[(2)]: 6147-53-1
Analytical methods[(3)]	1. For the identification of acetate in the additive: • European Pharmacopoeia monograph 01/2008:20301[(4)] 2. For the crystallographic characterisation of additive: • X-Ray diffraction 3. For the determination of total cobalt in the additive, premixtures, compound feed and feed materials: • 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)] 4. For determination of particle size distribution: • Particle size analysis — Laser diffraction methods in accordance with BS ISO 13320:2020[(7)]
Species or category of animal	Ruminants with a functional rumen, equidae, lagomorphs, rodents, herbivore reptiles and zoo mammals
Maximum age	No maximum

Column 1		*Column 2*
Element (Co) in mg/kg of complete feed with a moisture content of 12%	*Minimum content*	No minimum
	Maximum content	1 (total)
Other provisions		1. The additive must be incorporated into compound feed in the form of a premixture. 2. The following declarations must be made on the labelling of the additive and premixture: • 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 declaration must be made on the instructions of use of the compound feed: • "Protective measures to avoid exposure with cobalt by inhalation or by dermal route should be taken.".
Start of period of authorisation		15 July 2023
End of period of authorisation		14 July 2026

(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 preparation by the Chemical Abstracts Service https://cas.org/cas-data/cas-registry.

(3) Details of the analytical methods are available at the following address of the European Commission's Joint Research Centre: https://joint-research-centre.ec.europa.eu/publications/fad-cobalt-group_en.

(4) European Pharmacopoeia monograph 01/2008:20301 'Identification of ions and functional groups – *Sulphates*'. 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 31 August 2017 (ISBN 978 0 539 09335 3). 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 31 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 31 July 2020 (ISBN 978 0 580 92329 6). Available from the British Standards Institution https://knowledge.bsigroup.com.

SCHEDULE 2

Regulation 3(2)

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, subject to the conditions set out in the table.

Column 1	*Column 2*
Additive	Cobalt(II) carbonate
Identification number of the additive	3b302
Authorisation holder[(1)]	
Additive category	Nutritional additives
Functional group	Compounds of trace elements
Additive composition	Cobalt(II) carbonate, as a powder, with a minimum content of 46% cobalt Cobalt carbonate: minimum 75 % Cobalt hydroxide: 3% - 15% Water: maximum 6 % Particles < 11 μm: below 90%
Characterisation of the active substance(s)	Chemical formula: $CoCO_3$ CAS number[(2)]: 513-79-1
Analytical methods[(3)]	1. For the identification of carbonate in the additive: • European Pharmacopoeia monograph 01/2008:20301[(4)] 2. For the crystallographic characterisation of additive: • X-Ray diffraction 3. For the determination of total cobalt in the additive, premixtures, compound feed and feed materials: • 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 1521:2017[(6)] 4. For determination of particle size distribution:

Column 1		*Column 2*
		• Particle size analysis — laser diffraction methods in accordance with BS ISO 13320:2020[7]
Species or category of animal		Ruminants with a functional rumen, equidae, lagomorphs, rodents, herbivore reptiles and zoo mammals
Maximum age		No maximum
Element (Co) in mg/kg of complete feed with a moisture content of 12%	*Minimum content*	No minimum
	Maximum content	1 (total)
Other provisions		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-powder form. 2. The following declarations must be made on the labelling of the additive and premixture: • 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 declaration must be made on the instructions of use of the compound feed: • "Protective measures to avoid exposure with cobalt by inhalation or by dermal route should be taken.".
Start of period of authorisation		15 July 2023
End of period of authorisation		14 July 2026

(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 preparation by the Chemical Abstracts Service https://cas.org/cas-data/cas-registry.

(3) Details of the analytical methods are available at the following address of the European Commission's Joint Research Centre: https://joint-research-centre.ec.europa.eu/publications/fad-cobalt-group_en.

(4) European Pharmacopoeia monograph 01/2008:20301 'Identification of ions and functional groups – *Sulphates*'. 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 31 August 2017 (ISBN 978 0 539 09335 3). 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 31 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 31 July 2020 (ISBN 978 0 580 92329 6). Available from the British Standards Institution https://knowledge.bsigroup.com.

SCHEDULE 3

Regulation 3(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, subject to the conditions set out in the table.

Column 1	*Column 2*
Additive	Cobalt(II) carbonate hydroxide (2:3) monohydrate
Identification number of the additive	3b303
Authorisation holder[(1)]	
Additive category	Nutritional additives
Functional group	Compounds of trace elements
Additive composition	Cobalt(II) carbonate hydroxide (2:3) monohydrate, as powder, with a minimum content of 50% cobalt Particles < 50 µm: below 98%
Characterisation of the active substance(s)	Chemical formula: $2CoCO_3 \times 3Co(OH)_2 \times H_2O$ CAS number[(2)]: 51839-24-8
Analytical methods[(3)]	1. For the identification of carbonate in the additive: • European Pharmacopoeia monograph 01/2008:20301[(4)] 2. For the crystallographic characterisation of additive: • X-Ray diffraction 3. For the determination of total cobalt in the additive, premixtures, compound feed and feed materials: • 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)] 4. For determination of particle size distribution:

Column 1		*Column 2*
		• Particle size analysis — Laser diffraction methods in accordance with BS ISO 13320:2020[7]
Species or category of animal		Ruminants with a functional rumen, equidae, lagomorphs, rodents, herbivore reptiles and zoo mammals
Maximum age		No maximum
Element (Co) in mg/kg of complete feed with a moisture content of 12%	*Minimum content*	No minimum
	Maximum content	1 (total)
Other provisions		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-powder form. 2. The following declarations must be made on the labelling of the additive and premixture: • 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 declaration must be made on the instructions of use of the compound feed: • "Protective measures to avoid exposure with cobalt by inhalation or by dermal route should be taken.".
Start of period of authorisation		15 July 2023
End of period of authorisation		14 July 2026

(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 preparation by the Chemical Abstracts Service https://cas.org/cas-data/cas-registry.

(3) Details of the analytical methods are available at the following address of the European Commission's Joint Research Centre: https://joint-research-centre.ec.europa.eu/publications/fad-cobalt-group_en.

(4) European Pharmacopoeia monograph 01/2008:20301 'Identification of ions and functional groups – *Sulphates*'. 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 31 August 2017 (ISBN 978 0 539 09335 3). 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 31 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 31 July 2020 (ISBN 978 0 580 92329 6). Available from the British Standards Institution https://knowledge.bsigroup.com.

SCHEDULE 4

Regulation 3(4)

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 specified in the table in this schedule, 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, subject to the conditions set out in the table.

Column 1	*Column 2*
Additive	Cobalt(II) sulphate heptahydrate
Identification number of the additive	3b305
Authorisation holder[(1)]	
Additive category	Nutritional additives
Functional group	Compounds of trace elements
Additive composition	Cobalt(II) sulphate heptahydrate, as powder, with a minimum content of 20% cobalt Particles < 50µm: below 95%
Characterisation of the active substance(s)	Chemical formula: $CoSO_4 \times 7H_2O$ CAS number[(2)]: 10026-24-1
Analytical methods[(3)]	1. For the identification of sulphate in the additive: • European Pharmacopoeia monograph 01/2008:20301[(4)] 2. For the crystallographic characterisation of additive: • X-Ray diffraction 3. For the determination of total cobalt in the additive, premixtures, compound feed and feed materials: • 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)] 4. For determination of particle size distribution:

Column 1		*Column 2*
		• Particle size analysis — Laser diffraction methods in accordance with BS ISO 13320:2020[7]
Species or category of animal		Ruminants with a functional rumen, equidae, lagomorphs, rodents, herbivore reptiles and zoo mammals
Maximum age		Not applicable
Element (Co) in mg/kg of complete feed with a moisture content of 12%	*Minimum content*	No minimum
	Maximum content	1 (total)
Other provisions		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-powder form. 2. The following declarations must be made on the labelling of the additive and premixture: • 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 declaration must be made on the instructions of use of the compound feed: • "Protective measures to avoid exposure with cobalt by inhalation or by dermal route should be taken.".
Start of period of authorisation		15 July 2023
End of period of authorisation		14 July 2026

(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 preparation by the Chemical Abstracts Service https://cas.org/cas-data/cas-registry.

(3) Details of the analytical methods are available at the following address of the European Commission's Joint Research Centre: https://joint-research-centre.ec.europa.eu/publications/fad-cobalt-group_en.

(4) European Pharmacopoeia monograph 01/2008:20301 'Identification of ions and functional groups – *Sulphates*'. 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 31 August 2017 (ISBN 978 0 539 09335 3). 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 31 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 31 July 2020 (ISBN 978 0 580 92329 6). Available from the British Standards Institution https://knowledge.bsigroup.com.