

## II

(Non-legislative acts)

## REGULATIONS

## COMMISSION IMPLEMENTING REGULATION (EU) 2017/1490

of 21 August 2017

concerning the authorisation of manganous chloride tetrahydrate, manganese (II) oxide, manganous sulphate monohydrate, manganese chelate of amino acids hydrate, manganese chelate of protein hydrolysates, manganese chelate of glycine hydrate and dimanganous chloride trihydroxide as feed additives for all animal species

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (¹), and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC (²).
- (2) The manganese compounds manganous chloride tetrahydrate, manganous oxide, manganous sulphate monohydrate, manganese chelate of amino acids hydrate and manganese chelate of glycine hydrate were authorised without a time limit by Commission Regulations (EC) No 1334/2003 (³) and (EC) No 479/2006 (⁴) in accordance with Directive 70/524/EEC. Those substances were subsequently entered in the Register of feed additives as existing products, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.
- (3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, applications were submitted for the re-evaluation of manganous chloride tetrahydrate, manganous oxide, manganous sulphate monohydrate, manganese chelate of amino acids hydrate and manganese chelate of glycine hydrate as feed additives for all animal species. Additionally, in accordance with Article 7 of that Regulation, an application was submitted for manganese hydroxychloride as feed additive for all animal species. The applicants requested that those additives be classified in the additive category 'nutritional additives'. The applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinions of 23 October 2014 (⁵), 23 October 2014 (⁶), 19 March 2015 (⁷), 18 February 2016 (⁸) and 13 May 2016 (⁹) that, under the proposed

(¹) OJ L 268, 18.10.2003, p. 29.

(²) Council Directive 70/524/EEC of 23 November 1970 concerning additives in feeding-stuffs (OJ L 270, 14.12.1970, p. 1).

(³) Commission Regulation (EC) No 1334/2003 of 25 July 2003 amending the conditions for authorisation of a number of additives in feedingstuffs belonging to the group of trace elements (OJ L 187, 26.7.2003, p. 11).

(⁴) Commission Regulation (EC) No 479/2006 of 23 March 2006 as regards the authorisation of certain additives belonging to the group compounds of trace elements (OJ L 86, 24.3.2006, p. 4).

(⁵) EFSA Journal 2013;11(8):3324.

(⁶) EFSA Journal 2013;11(8):3325.

(⁷) EFSA Journal 2013;11(10):3435.

(⁸) EFSA Journal 2016;14(2):4395.

(⁹) EFSA Journal 2016;14(5):4474.

conditions of use, manganous chloride tetrahydrate, manganese (II) oxide, manganous sulphate monohydrate, manganese chelate of amino acids hydrate, manganese chelate of protein hydrolysates, manganese chelate of glycine hydrate and dimanganese chloride trihydroxide do not have an adverse effect on animal health, consumer safety and the environment. Due to scientific considerations, the Authority recommended to rename manganous oxide as manganese (II) oxide and manganese hydroxychloride as dimanganese chloride trihydroxide, in order to avoid potential misunderstandings. The Authority also recommended splitting manganese chelate of amino acids into the following two groups, in view of its chemical characteristics: manganese chelate of amino acids hydrate and manganese chelate of protein hydrolysates.

(5) The Authority noted that handling manganese (II) oxide is hazardous by inhalation to the user. In the absence of adequate data, the additive should be considered as a potential skin and eye irritant and as a dermal sensitiser. The Authority also noted that handling manganous sulphate monohydrate poses a risk to users upon inhalation exposure and is an eye irritant. It was also observed that handling manganese chelate of amino acids hydrate poses a possible hazard to the respiratory tract and the health of users. In the absence of adequate data regarding irritancy to the skin and eyes and dermal sensitisation, this latter additive should also be considered as a potential skin and eye irritant and as a skin and respiratory sensitiser. With respect to manganese chelate of glycine hydrate, the Authority noted that this additive may irritate skin and eyes. Finally, in the absence of specific data, the Authority could not conclude on the safety for the user when handling dimanganese chloride trihydroxide. Consequently, appropriate protective measures should be taken with respect to the additives concerned, in order to avoid that safety concerns for the users would arise.

(6) The Authority further concluded that manganous chloride tetrahydrate, manganese (II) oxide, manganous sulphate monohydrate, manganese chelate of amino acids hydrate, manganese chelate of protein hydrolysates, manganese chelate of glycine hydrate and dimanganese chloride trihydroxide are effective sources of manganese. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(7) The assessment of manganous chloride tetrahydrate, manganese (II) oxide, manganous sulphate monohydrate, manganese chelate of amino acids hydrate, manganese chelate of protein hydrolysates, manganese chelate of glycine hydrate and dimanganese chloride trihydroxide shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied, except for water for drinking. Accordingly, the use of these substances should be authorised as specified in the Annex to this Regulation and their use via water for drinking should be denied.

(8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for manganous chloride tetrahydrate, manganese oxide, manganous sulphate monohydrate, manganese chelate of amino acids hydrate and manganese chelate of glycine hydrate as authorised by Regulation (EC) No 1334/2003, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.

(9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

## Article 1

### **Authorisation**

The substances specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'compounds of trace elements', are authorised as feed additives in animal nutrition, subject to the conditions laid down in that Annex.

## Article 2

### **Denial**

Authorisation of the substances specified in the Annex as additives belonging to the additive category 'nutritional additives' and to the functional group 'compounds of trace elements' is denied for use in water for drinking.

### Article 3

#### Transitional measures

1. The substances manganous chloride tetrahydrate, manganous oxide, manganous sulphate monohydrate, manganese chelate of amino acids hydrate and manganese chelate of glycine hydrate as authorised by Regulations (EC) No 1334/2003 and (EC) No 479/2006, and premixtures containing those substances, which are produced and labelled before 11 March 2018 in accordance with the rules applicable before 11 September 2017 may continue to be placed on the market and used until the existing stocks are exhausted.

2. Feed materials and compound feed containing the substances referred to in paragraph 1 which are produced and labelled before 11 September 2018 in accordance with the rules applicable before 11 September 2017 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.

3. Feed materials and compound feed containing the substances referred to in paragraph 1 which are produced and labelled before 11 September 2019 in accordance with the rules applicable before 11 September 2017 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

### Article 4

#### Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 21 August 2017.

*For the Commission*

*The President*

Jean-Claude JUNCKER

## ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Content of element (Mn) in mg/kg of complete feed with a moisture content of 12 %			

## Category of nutritional additives. Functional group: compounds of trace elements

3b501	—	Manganous chloride tetrahydrate	<p><i>Additive composition</i> Manganous chloride tetrahydrate, as a powder, with a minimum content of 27 % manganese.</p> <p><i>Characterisation of the active substance</i> Manganous chloride tetrahydrate Chemical formula: <math>MnCl_2 \cdot 4H_2O</math> CAS Number: 13446-34-9</p> <p><i>Analytical methods (1)</i> For the identification reactions of chloride in the feed additive: — European Pharmacopoeia Monograph 2.3.1;</p> <p>For the crystallographic characterisation of the feed additive: — X-Ray diffraction;</p> <p>For the quantification of total manganese in the feed additive and premixtures: — Atomic Absorption Spectrometry, AAS (EN ISO 6869); or — Inductively Coupled Plasma — Atomic Emission Spectrometry, ICP-AES (EN 15510); or</p>	All animal species	—	—	<p>Fish: 100 (total) Other species: 150 (total)</p>	<ol style="list-style-type: none"> <li>1. The additive shall be incorporated into feed in the form of a premixture.</li> <li>2. Manganous chloride tetrahydrate may be placed on the market and used as an additive consisting of a preparation.</li> <li>3. For users of the additive and premixtures, feed business operators shall establish operational procedures and appropriate organisational measures to address the potential risks by inhalation, dermal contact or eyes contact, in particular due to the content of heavy metals including nickel. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.</li> </ol>	11 September 2027
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Identifica- tion number of the addi- tive	Name of the holder of author- isation	Additive	Composition, chemical formula, descrip- tion, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
						Content of element (Mn) in mg/kg of complete feed with a moisture content of 12 %			
			<ul style="list-style-type: none"> <li>— Inductively Coupled Plasma — Atomic Emission Spectrometry after pressure digestion, ICP-AES (CEN/TS 15621);</li> </ul> <p>For the quantification of total manganese in feed materials and compound feed:</p> <ul style="list-style-type: none"> <li>— Atomic Absorption Spectrometry, AAS (Commission Regulation (EC) No 152/2009 (2), Annex IV-C); or</li> <li>— Atomic Absorption Spectrometry, AAS (EN ISO 6869); or</li> <li>— Inductively Coupled Plasma — Atomic Emission Spectrometry, ICP-AES (EN 15510); or</li> <li>— Inductively Coupled Plasma — Atomic Emission Spectrometry after pressure digestion, ICP-AES (CEN/TS 15621).</li> </ul>						
3b502	—	Manganese (II) oxide	<p><i>Additive composition</i></p> <p>Manganous oxide, as a powder, with a minimum content of 60 % manganese;</p> <p>Minimum content of 77,5 % MnO and a maximum content of 2 % MnO<sub>2</sub></p> <p><i>Characterisation of the active substance</i></p> <p>Manganous oxide</p> <p>Chemical formula: MnO</p> <p>CAS Number: 1344-43-0</p>	All animal species	—	—	<p>Fish: 100 (total)</p> <p>Other species: 150 (total)</p>	<ol style="list-style-type: none"> <li>1. The additive shall be incorporated into feed in the form of a premixture.</li> <li>2. Manganese (II) oxide may be placed on the market and used as an additive consisting of a preparation.</li> </ol>	11 Sep- tember 2027

Identifica- tion number of the additive	Name of the holder of author- isation	Additive	Composition, chemical formula, descrip- tion, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
						Content of element (Mn) in mg/kg of complete feed with a moisture content of 12 %			
			<p><i>Analytical methods (¹)</i></p> <p>For the crystallographic characterisation of the feed additive:</p> <ul style="list-style-type: none"> <li>— X-Ray diffraction;</li> </ul> <p>For the quantification of total manganese in the feed additive and premixtures:</p> <ul style="list-style-type: none"> <li>— Atomic Absorption Spectrometry, AAS (EN ISO 6869); or</li> <li>— Inductively Coupled Plasma — Atomic Emission Spectrometry, ICP-AES (EN 15510); or</li> <li>— Inductively Coupled Plasma — Atomic Emission Spectrometry after pressure digestion, ICP-AES (CEN/TS 15621);</li> </ul> <p>For the quantification of total manganese in feed materials and compound feed:</p> <ul style="list-style-type: none"> <li>— Atomic Absorption Spectrometry, AAS (Regulation (EC) No 152/2009, Annex IV-C); or</li> <li>— Atomic Absorption Spectrometry, AAS (EN ISO 6869); or</li> <li>— Inductively Coupled Plasma — Atomic Emission Spectrometry, ICP-AES (EN 15510); or</li> <li>— Inductively Coupled Plasma — Atomic Emission Spectrometry after pressure digestion, ICP-AES (CEN/TS 15621).</li> </ul>					<p>3. For users of the additive and premixtures, feed business operators shall establish operational procedures and appropriate organisational measures to address the potential risks by inhalation, dermal contact or eyes contact, in particular due to the content of heavy metals including nickel. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.</p>	

Identifica- tion number of the addi- tive	Name of the holder of author- isation	Additive	Composition, chemical formula, descrip- tion, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
						Content of element (Mn) in mg/kg of complete feed with a moisture content of 12 %			
3b503	—	Manganous sulphate monohydrate	<p><i>Additive composition</i></p> <p>Manganous sulphate monohydrate, as a powder, with a minimum content of 95 % manganous sulphate monohydrate and of 31 % manganese.</p> <p><i>Characterisation of the active substance</i></p> <p>Manganous sulphate monohydrate</p> <p>Chemical formula: <math>\text{MnSO}_4 \cdot \text{H}_2\text{O}</math></p> <p>CAS Number: 10034-96-5</p> <p><i>Analytical methods (1)</i></p> <p>For the quantification of the manganous sulphate monohydrate in the feed additive:</p> <ul style="list-style-type: none"> <li>— titration with ammonium and cerium nitrate (Ph. Eur Monograph 1543);</li> </ul> <p>For the identification reactions of sulphates in the feed additive:</p> <ul style="list-style-type: none"> <li>— European Pharmacopoeia Monograph 2.3.1;</li> </ul> <p>For the crystallographic characterisation of the feed additive:</p> <ul style="list-style-type: none"> <li>— X-Ray diffraction;</li> </ul> <p>For the quantification of total manganese in the feed additive and premixtures:</p> <ul style="list-style-type: none"> <li>— Atomic Absorption Spectrometry, AAS (EN ISO 6869); or</li> <li>— Inductively Coupled Plasma — Atomic Emission Spectrometry, ICP-AES (EN 15510); or</li> </ul>	All animal species	—	—	<p>Fish: 100 (total)</p> <p>Other species: 150 (total)</p>	<ol style="list-style-type: none"> <li>1. The additive shall be incorporated into feed in the form of a premixture.</li> <li>2. Manganous sulphate monohydrate may be placed on the market and used as an additive consisting of a preparation.</li> <li>3. For users of the additive and premixtures, feed business operators shall establish operational procedures and appropriate organisational measures to address the potential risks by inhalation, dermal contact or eyes contact, in particular due to the content of heavy metals including nickel. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.</li> </ol>	11 Sep- tember 2027

Identifica- tion number of the addi- tive	Name of the holder of author- isation	Additive	Composition, chemical formula, descrip- tion, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
						Content of element (Mn) in mg/kg of complete feed with a moisture content of 12 %			
			<ul style="list-style-type: none"> <li>— Inductively Coupled Plasma — Atomic Emission Spectrometry after pressure digestion, ICP-AES (CEN/TS 15621);</li> </ul> <p>For the quantification of total manganese in feed materials and compound feed:</p> <ul style="list-style-type: none"> <li>— Atomic Absorption Spectrometry, AAS (Regulation (EC) No 152/2009, Annex IV-C); or</li> <li>— Atomic Absorption Spectrometry, AAS (EN ISO 6869); or</li> <li>— Inductively Coupled Plasma — Atomic Emission Spectrometry, ICP-AES (EN 15510); or</li> <li>— Inductively Coupled Plasma — Atomic Emission Spectrometry after pressure digestion, ICP-AES (CEN/TS 15621).</li> </ul>						
3b504	—	Manganese chelate of amino acids hydrate	<p><i>Additive composition</i></p> <p>Manganese amino acid complex where the manganese and the amino acids derived from soya protein are chelated via coordinate covalent bonds, as a powder with a minimum content of 8 % manganese.</p> <p><i>Characterisation of the active substance</i></p> <p>Chemical formula: <math>Mn(x)_{1-3} \cdot nH_2O</math>, x = anion of any amino acid derived from acid hydrolysed soya protein;</p> <p>Maximum of 10 % of the molecules exceeding 1 500 Da.</p>	All animal species	—	—	<p>Fish: 100 (total)</p> <p>Other species: 150 (total)</p>	<ol style="list-style-type: none"> <li>1. The additive shall be incorporated into feed in the form of a premixture.</li> <li>2. Manganese chelate of amino acids hydrate may be placed on the market and used as an additive consisting of a preparation.</li> </ol>	11 Sep- tember 2027

Identifica- tion number of the addi- tive	Name of the holder of author- isation	Additive	Composition, chemical formula, descrip- tion, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
						Content of element (Mn) in mg/kg of complete feed with a moisture content of 12 %			
			<p><i>Analytical methods (1)</i></p> <p>For the quantification of amino acid content in the feed additive:</p> <ul style="list-style-type: none"> <li>— ion exchange chromatography combined with post-column ninhydrin derivatisation and photometric detection (Regulation (EC) No 152/2009, Annex III, F);</li> </ul> <p>For the quantification of total manganese in the feed additive and premixtures:</p> <ul style="list-style-type: none"> <li>— Atomic Absorption Spectrometry, AAS (EN ISO 6869); or</li> <li>— Inductively Coupled Plasma — Atomic Emission Spectrometry, ICP-AES (EN 15510); or</li> <li>— Inductively Coupled Plasma — Atomic Emission Spectrometry after pressure digestion, ICP-AES (CEN/TS 15621);</li> </ul> <p>For the quantification of total manganese in feed materials and compound feed:</p> <ul style="list-style-type: none"> <li>— Atomic Absorption Spectrometry, AAS (Regulation (EC) No 152/2009, Annex IV-C); or</li> <li>— Atomic Absorption Spectrometry, AAS (EN ISO 6869); or</li> <li>— Inductively Coupled Plasma — Atomic Emission Spectrometry, ICP-AES (EN 15510); or</li> <li>— Inductively Coupled Plasma — Atomic Emission Spectrometry after pressure digestion, ICP-AES (CEN/TS 15621).</li> </ul>					<p>3. For users of the additive and premixtures, feed business operators shall establish operational procedures and appropriate organisational measures to address the potential risks by inhalation, dermal contact or eyes contact, in particular due to the content of heavy metals including nickel. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.</p>	

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						Content of element (Mn) in mg/kg of complete feed with a moisture content of 12 %			
3b505	—	Manganese chelate of protein hydrolysates	<p><b>Additive composition</b></p> <p>Manganese chelate of protein hydrolysates as a powder with a minimum content of 10 % manganese.</p> <p>Minimum of 50 % manganese chelated.</p> <p><b>Characterisation of the active substance</b></p> <p>Chemical formula: <math>Mn(x)_{1-3} \cdot nH_2O</math>, x = anion of protein hydrolysates containing any amino acid from soya protein hydrolysate.</p> <p><b>Analytical methods (¹)</b></p> <p>For the quantification of protein hydrolysates content in the feed additive:</p> <ul style="list-style-type: none"> <li>— ion exchange chromatography combined with post-column ninhydrin derivatisation and photometric detection (Regulation (EC) No 152/2009, Annex III, F);</li> </ul> <p>For the determination of chelated manganese content in the feed additive:</p> <ul style="list-style-type: none"> <li>— Fourier Transformed Infrared (FTIR) spectroscopy followed by multivariate regression methods.</li> </ul> <p>For the quantification of total manganese in the feed additive and premixtures:</p> <ul style="list-style-type: none"> <li>— Atomic Absorption Spectrometry, AAS (EN ISO 6869); or</li> </ul>	All animal species	—	—	<p>Fish: 100 (total)</p> <p>Other species: 150 (total)</p>	<ol style="list-style-type: none"> <li>1. The additive shall be incorporated into feed in the form of a premixture.</li> <li>2. Manganese chelate of protein hydrolysates may be placed on the market and used as an additive consisting of a preparation.</li> <li>3. For users of the additive and premixtures, feed business operators shall establish operational procedures and appropriate organisational measures to address the potential risks by inhalation, dermal contact or eyes contact, in particular due to the content of heavy metals including nickel. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.</li> </ol>	11 September 2027

Identifica- tion number of the addi- tive	Name of the holder of author- isation	Additive	Composition, chemical formula, descrip- tion, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
						Content of element (Mn) in mg/kg of complete feed with a moisture content of 12 %			
			<ul style="list-style-type: none"> <li>— Inductively Coupled Plasma — Atomic Emission Spectrometry, ICP-AES (EN 15510); or</li> <li>— Inductively Coupled Plasma — Atomic Emission Spectrometry after pressure digestion, ICP-AES (CEN/TS 15621);</li> </ul> <p>For the quantification of total manganese in feed materials and compound feed:</p> <ul style="list-style-type: none"> <li>— Atomic Absorption Spectrometry, AAS (Regulation (EC) No 152/2009, Annex IV-C); or</li> <li>— Atomic Absorption Spectrometry, AAS (EN ISO 6869); or</li> <li>— Inductively Coupled Plasma — Atomic Emission Spectrometry, ICP-AES (EN 15510); or</li> <li>— Inductively Coupled Plasma — Atomic Emission Spectrometry after pressure digestion, ICP-AES (CEN/TS 15621).</li> </ul>						
3b506	—	Manganese chelate of glycine hydrate	<p><i>Additive composition</i> Manganese chelate of glycine, hydrate, as a powder with a minimum content of 15 % manganese. Moisture: maximum 10 %.</p> <p><i>Characterisation of the active substance</i> Chemical formula: <math>Mn(x)_{1-3} \cdot nH_2O</math>, x = anion of glycine.</p>	All animal species	—	—	<p>Fish: 100 (total) Other species: 150 (total)</p>	<ol style="list-style-type: none"> <li>1. The additive shall be incorporated into feed in the form of a premixture.</li> <li>2. Manganese chelate of glycine hydrate may be placed on the market and used as an additive consisting of a preparation.</li> </ol>	11 September 2027

Identifica- tion number of the addi- tive	Name of the holder of author- isation	Additive	Composition, chemical formula, descrip- tion, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
						Content of element (Mn) in mg/kg of complete feed with a moisture content of 12 %			
			<p><i>Analytical methods (1)</i></p> <p>For the quantification of the glycine content in the feed additive:</p> <ul style="list-style-type: none"> <li>— ion exchange chromatography combined with post-column ninhydrin derivatisation and photometric detection (Regulation (EC) No 152/2009, Annex III, F);</li> </ul> <p>For the quantification of total manganese in the feed additive and premixtures:</p> <ul style="list-style-type: none"> <li>— Atomic Absorption Spectrometry, AAS (EN ISO 6869); or</li> <li>— Inductively Coupled Plasma — Atomic Emission Spectrometry, ICP-AES (EN 15510); or</li> <li>— Inductively Coupled Plasma — Atomic Emission Spectrometry after pressure digestion, ICP-AES (CEN/TS 15621);</li> </ul> <p>For the quantification of total manganese in feed materials and compound feed:</p> <ul style="list-style-type: none"> <li>— Atomic Absorption Spectrometry, AAS (Regulation (EC) No 152/2009, Annex IV-C); or</li> <li>— Atomic Absorption Spectrometry, AAS (EN ISO 6869); or</li> <li>— Inductively Coupled Plasma — Atomic Emission Spectrometry, ICP-AES (EN 15510); or</li> <li>— Inductively Coupled Plasma — Atomic Emission Spectrometry after pressure digestion, ICP-AES (CEN/TS 15621).</li> </ul>					<p>3. For users of the additive and premixtures, feed business operators shall establish operational procedures and appropriate organisational measures to address the potential risks by inhalation, dermal contact or eyes contact, in particular due to the content of heavy metals including nickel. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.</p>	

Identifica- tion number of the addi- tive	Name of the holder of author- isation	Additive	Composition, chemical formula, descrip- tion, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
						Content of element (Mn) in mg/kg of complete feed with a moisture content of 12 %			
3b507	—	Dimanganese chloride tri- hydroxide	<p><b>Additive composition</b> Granulate powder with a minimum content of 44 % manganese and a maximum content of 7 % manganese oxide</p> <p><b>Characterisation of the active substance</b> Dimanganese chloride trihydroxide Chemical formula: Mn<sub>2</sub>(OH)<sub>3</sub>Cl CAS Number: 39438-40-9</p> <p><b>Analytical methods (1)</b> For the identification of the crystallographic characterisation of the feed additive: — X-Ray diffraction;</p> <p>For the quantification of chlorine in the feed additive: — Titration — Regulation (EC) No 152/2009;</p> <p>For the quantification of total manganese in the feed additive and premixtures: — Atomic Absorption Spectrometry, AAS (EN ISO 6869); or — Inductively Coupled Plasma — Atomic Emission Spectrometry, ICP-AES (EN 15510); or — Inductively Coupled Plasma — Atomic Emission Spectrometry after pressure digestion, ICP-AES (CEN/TS 15621);</p>	All animal species	—	—	Fish: 100 (total) Other species: 150 (total)	<ol style="list-style-type: none"> <li>1. The additive shall be incorporated into feed in the form of a premixture.</li> <li>2. Dimanganese chloride trihydroxide may be placed on the market and used as an additive consisting of a preparation.</li> <li>3. For users of the additive and premixtures, feed business operators shall establish operational procedures and appropriate organisational measures to address the potential risks by inhalation, dermal contact or eyes contact, in particular due to the content of heavy metals including nickel. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.</li> </ol>	11 September 2027

Identifica- tion number of the addi- tive	Name of the holder of author- isation	Additive	Composition, chemical formula, descrip- tion, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
						Content of element (Mn) in mg/kg of complete feed with a moisture content of 12 %			
			<p>For the quantification of total manganese in feed materials and compound feed:</p> <ul style="list-style-type: none"> <li>— Atomic Absorption Spectrometry, AAS (Regulation (EC) No 152/2009, Annex IV-C); or</li> <li>— Atomic Absorption Spectrometry, AAS (EN ISO 6869); or</li> <li>— Inductively Coupled Plasma — Atomic Emission Spectrometry, ICP-AES (EN 15510); or</li> <li>— Inductively Coupled Plasma — Atomic Emission Spectrometry after pressure digestion, ICP-AES (CEN/TS 15621).</li> </ul>						

(<sup>1</sup>) Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

(<sup>2</sup>) Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for official control of feed (OJ L 54, 26.2.2009, p. 1).