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COMMISSION IMPLEMENTING REGULATION (EU) 2019/804

of 17 May 2019

concerning the renewal of the authorisation of organic form of selenium produced by *Saccharomyces cerevisiae* CNCM I-3060 and of selenomethionine produced by *Saccharomyces cerevisiae* NCYC R397 as feed additives for all animal species and repealing Regulations (EC) No 1750/2006 and (EC) No 634/2007

(Text with EEA relevance)

(OJ L 132, 20.5.2019, p. 28)

Amended by:

		Official Journal		
		No	page	date
►**M1**	Commission Implementing Regulation (EU) 2022/1459 of 2 September 2022	L 229	22	5.9.2022

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COMMISSION IMPLEMENTING REGULATION (EU) 2019/804

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(Text with EEA relevance)

Article 1

The authorisation of the additives specified in the Annex, belonging to the additive category ‘nutritional additives’ and to the functional group ‘compounds of trace elements’, is renewed subject to the conditions laid down in that Annex.

Article 2

1. The organic form of selenium produced by *Saccharomyces cerevisiae* CNCM I-3060, selenomethionine produced by *Saccharomyces cerevisiae* NCYC R397 and premixtures containing these substances, which are produced and labelled before 9 December 2019 in accordance with the rules applicable before 9 June 2019 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 point 1, which are produced and labelled before 9 June 2020 in accordance with the rules applicable before 9 June 2019 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 point 1, which are produced and labelled before 9 June 2021 in accordance with the rules applicable before 9 June 2019 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 3

Regulations (EC) No 1750/2006 and (EC) No 634/2007 are repealed.

Article 4

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.

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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
						Selenium in mg/kg of complete feed with a moisture content of 12 %			
Category of nutritional additives. Functional group: compounds of trace elements									
▼M1									
3b810	—	Selenised yeast *Saccharomyces cerevisiae* CNCM I-3060, inactivated	*Additive composition* Preparation of organic selenium: Content of selenium: 2 000 to 2 400 mg Se/kg Organic selenium > 97 to 99 % of total selenium Selenomethionine > 63 % of total selenium *Characterisation of the active substance* Selenomethionine produced by *Saccharomyces cerevisiae* CNCM I-3060 Chemical formula: $C_5H_{11}NO_2Se$ *Analytical method* (1): For the determination of selenomethionine in the feed additive:	All species	—		0,50 (total)	1. The additive shall be incorporated into feed in the form of a premixture. 2. The directions for use of the additive and premixtures shall indicate the storage and stability conditions. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment.	9 June 2029

▼M1

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
						Selenium in mg/kg of complete feed with a moisture content of 12 %			
			— reversed phase high performance liquid chromatography with UV detection (RP-HPLC-UV) or — high performance liquid chromatography and inductively coupled plasma mass spectrometry (HPLC-ICPMS) after triple proteolytic digestion. For the determination of total selenium in the feed additive: — inductively coupled plasma atomic emission spectrometry (ICP-AES) or — inductively coupled plasma mass spectrometry (ICPMS). For the determination of total selenium in premixtures, compound feed and feed materials: — hydride generation atomic absorption spectrometry (HGAAS) after microwave digestion (EN 16159:2012).					4. Maximum supplementation with organic selenium: 0,2 mg Se/kg of complete feed with a moisture content of 12 %.	

▼M1

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
						Selenium in mg/kg of complete feed with a moisture content of 12 %			
3b810i	—	Selenised yeast *Saccharomyces cerevisiae* CNCM I-3060, inactivated	*Additive composition* Preparation of organic selenium: Content of selenium 3 000-3 500 mg Se/kg Organic selenium > 97 to 99 % of total selenium Selenomethionine > 63 % of total selenium *Characterisation of the active substance* Selenomethionine produced by *Saccharomyces cerevisiae* CNCM I-3060 Chemical formula: $C_5H_{11}NO_2Se$ *Analytical method* (1) For the determination of selenomethionine in the feed additive:	All species	—		0,50 (total)	1. The additive shall be incorporated into feed in the form of a premixture. 2. The directions for use of the additive and premixtures shall indicate the storage and stability conditions. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection. 4. Maximum supplementation with organic selenium:	9 June 2029

▼M1

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
						Selenium in mg/kg of complete feed with a moisture content of 12 %			
			— reversed phase high performance liquid chromatography with UV detection (RP-HPLC-UV) or — high performance liquid chromatography and inductively coupled plasma mass spectrometry (HPLC-ICPMS) after triple proteolytic digestion. For the determination of total selenium in the feed additive: — inductively coupled plasma atomic emission spectrometry (ICP-AES) or — inductively coupled plasma mass spectrometry (ICPMS). For the determination of total selenium in premixtures, compound feed and feed materials: — hydride generation atomic absorption spectrometry (HGAAS) after microwave digestion (EN 16159:2012).					0,2 mg Se/kg of complete feed with a moisture content of 12 %. 5. The dusting potential of the additive shall ensure a maximal Se exposure of 0,2 mg Se/m^3	

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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
						Selenium in mg/kg of complete feed with a moisture content of 12 %			
3b811	—	Selenised yeast *Saccharomyces cerevisiae* NCYC R397, inactivated	*Additive composition* Preparation of organic selenium: Content of selenium: 2 000 to 3 500 mg Se/kg Organic selenium > 98 % of total selenium Selenomethionine > 63 % of total selenium *Characterisation of the active substance* Selenomethionine produced by *Saccharomyces cerevisiae* NCYC R397 Chemical formula: $C_5H_{11}NO_2Se$ *Analytical method* (1) For the determination of selenomethionine in the feed additive: — reversed phase high performance liquid chromatography with UV detection (RP-HPLC-UV) or	All species	—		0,50 (total)	1. The additive shall be incorporated into feed in the form of a premixture. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation, dermal, mucosae or eye contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection, safety glasses and gloves. 3. In the directions for use of the additive and premixtures, indicate the storage and stability conditions.	9 June 2029

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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
						Selenium in mg/kg of complete feed with a moisture content of 12 %			
			— high performance liquid chromatography and inductively coupled plasma mass spectrometry (HPLC-ICPMS) after triple proteolytic digestion. For the determination of total selenium in the feed additive: — inductively coupled plasma atomic emission spectrometry (ICP-AES) or — inductively coupled plasma mass spectrometry (ICPMS). For the determination of total selenium in premixtures, compound feed and feed materials: — hydride generation atomic absorption spectrometry (HGAAS) after microwave digestion (EN 16159:2012).					4. Maximum supplementation with organic selenium: 0,20 mg Se/kg of complete feed with a moisture content of 12 %.	

([1]) Details of the analytical methods are available at the following address of the European Union Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en