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COMMISSION IMPLEMENTING REGULATION (EU) 2023/60

of 5 January 2023

concerning the authorisation of conjugated linoleic acid (t10, c12)-methylester as a feed additive for pigs for fattening and dairy cows (holder of authorisation: ►M1 Louis Dreyfus Company Ingredients GmbH ◄)

(Text with EEA relevance)

(OJ L 5, 6.1.2023, p. 19)

Amended by:

		Official Journal		
		No	page	date
►M1	Commission Implementing Regulation (EU) 2026/1158 of 28 May 2026	L 1158	1	29.5.2026

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(Text with EEA relevance)

Article 1

The substance specified in the Annex, belonging to the additive category ‘zootechnical additives’ and to the functional group ‘other zootechnical additives’, is authorised as a feed additive for fattening pigs and dairy cows, in accordance with the conditions laid down in that Annex.

Article 2

1. The substance specified in the Annex and premixtures containing that substance, which are intended for pigs for fattening and dairy cows and are produced and labelled before 26 July 2023 in accordance with the rules applicable before 26 January 2023 may continue to be placed on the market and used until the existing stocks are exhausted.

2. Feed materials and compound feed containing the substance specified in the Annex, which are intended for pigs for fattening and dairy cows and are produced and labelled before 26 January 2024 in accordance with the rules applicable before 26 January 2023 may continue to be placed on the market and used until the existing stocks are exhausted.

Article 3

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
						mg of active substance/kg of complete feedingstuff with a moisture content of 12 %			
Category of Zootechnical additives. Functional group: Other zootechnical additives (improvement of zootechnical parameters/performance)									
4d895	►**M1** Louis Dreyfus Company Ingredients GmbH ◄	Conjugated linoleic acid (t10, c12)-methylester	*Additive composition:* Preparation of omega-6-fatty acid as t10,c12-octadecadienoic acid (conjugated linoleic acid)-methylester (CLA(t10,c12)-ME). Liquid formulation: CLA (t10,c12)-ME ≥ 28 % CLA (c9,t11)-ME ≥ 28 % CLA (t10,c12) < 2 % CLA (c9,t11) < 2 % Fatty acids of sunflower oil: 38-42 % free or as methylesters and less than 1 % as trans trans isomers. Solid formulation: CLA (t10,c12)-ME: ≥ 9 % CLA (c9,t11)-ME: ≥ 9 % CLA (t10,c12): < 1 % CLA (c9,t11): < 1 % Fatty acids of sunflower oil:13-15 % (free or as methylesters). Vegetable oils (hydrogenated triglycerides, predominantly stearic acid and to a minor extent palmitic acid): 44,5 %. Colloidal silica: 15 %. Calcium sulphate: 5 %.	Pigs for fattening	-	400	5 000	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. For dairy cows, the level of CLA (t10,c12)-ME in the daily ration shall not exceed 10 g/head/day. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential health risks resulting from their use. 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 eye and skin protection.	26.1.2033
				Dairy cows		175	350		
					-	-			

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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
						mg of active substance/kg of complete feedingstuff with a moisture content of 12 %			
Category of Zootechnical additives. Functional group: Other zootechnical additives (improvement of zootechnical parameters/performance)									
			Characterisation of the active substance: Conjugated linoleic acid (t10,c12)-methylester. Chemical formula: C_{19} $H_{34}O_2$ CAS number: 21870-97-3 *Analytical method :* ([1]) — For the determination of Omega-6-fatty acid as octadecadienoic acid (trans-10, cis-12- isomer) in feed additive: gas Chromatography coupled to Flame Ionization Detector (GC-FID) — For the quantification of CLA (t10,c12)-methylester in premixtures and feedingstuffs: — high performance liquid chromatography coupled to spectrophotometric detection (HPLC-UV)						

([1]) 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.