

EN
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 of kg of complete feedingstuff feed with a moisture content of 12 %			
Category of Zootechnical additives. Functional group: Other zootechnical additives (improvement of zootechnical parameters/performance)									
4d895	BASF SE	Conjugated linoleic acid (t10, c12)-methyl ester.	<p>Additive composition: Preparation of omega-6-fatty acid as t10,c12- octadecadienoic acid (conjugated linoleic acid)-methyl ester (CLA(t10,c12)-ME).</p> <p><u>Liquid formulation:</u> 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 methyl esters and less than 1% as trans isomers.</p>	Pigs for fattening Dairy cows	-	400 175	5000 350	<ol style="list-style-type: none"> 1. In the directions for use of the additive and premixture, 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 	<p><i>[to be completed by the Service responsible for the publication: insert precise date]</i></p> <p>[10 years from the date of entry into force of this Regulation]</p>

		<p>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%.</p> <p>-----</p> <p>Characterisation of the active substance: Conjugated linoleic acid (t10,c12)-methylester. Chemical formula: C₁₉ H₃₄O₂ CAS number: 21870-97-3</p> <p>-----</p> <p>Analytical method¹ 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).</p>		-	-		<p>business operators shall establish operational procedures and organisational measures to address potential risks resulting from its 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.</p>
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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>