

**ANNEX**

Identification number of the feed additive	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 1,25-dihydroxycholecalciferol /kg of complete feedingstuff with a moisture content of 12 %		
<b>Category of nutritional additives. Functional group: vitamins, pro-vitamins and chemically well-defined substances having similar effect. Subclassification: Vitamin D</b>								
3a673	Glycosylated 1,25-dihydroxycholecalciferol from <i>Solanum glaucophyllum</i> extract	<p><b>Additive composition</b> Preparation of <i>Solanum glaucophyllum</i> extract with a minimum of 0,005 % of glycosylated 1,25-dihydroxycholecalciferol Solid form</p> <p><b>Characterisation of active substance</b> Glycosylated 1,25-dihydroxycholecalciferol Chemical formula: <math>C_{27}H_{44}O_3 \cdot (C_6H_{10}O_5)_n</math>, where n= 1 to 12 CAS number: 89457-77-2 Produced by ethanolic extraction of leaves of <i>Solanum glaucophyllum</i></p>	Dairy cows	-	-	0,004	<ol style="list-style-type: none"> <li>The additive shall be only used for incorporation in a complementary feed (in the form of a bolus) to reduce the risk of milk fever and subclinical hypocalcaemia.</li> <li>The use of the additive shall be allowed only once during the pre-parturient period (from 9 days before calving to immediately before calving).</li> <li>The additive is administered once in a form of bolus with daily administration of: <ul style="list-style-type: none"> <li>a minimum of calcium of 60 g per cow during one week before calving and 84 g per day until the end of the third week of lactation<del>ag</del>;</li> <li>a minimum of magnesium of 18 g per</li> </ul> </li> </ol>	[10 years from the date of entry into force of this Regulation. To be completed by the OP]

Identification number of the feed additive	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
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<b>Category of nutritional additives. Functional group: vitamins, pro-vitamins and chemically well-defined substances having similar effect. Subclassification: Vitamin D</b>								
		<b>Analytical method<sup>1</sup></b> For the quantification of glycosylated 1,25-dihydroxycholecalciferol in the feed additive and in the feed (bolus): – Liquid chromatography coupled to tandem mass spectrometry (LC-MS/MS).					cow during one week before calving and 26 g until the end of the third week of lactation. 4. The directions for use of the additive shall indicate the storage conditions. 5. Maximum content of the combination of glycosylated 1,25-dihydroxycholecalciferol with vitamin D <sub>3</sub> (cholecalciferol) per kg of complete feed: 0,1 mg <sup>2</sup> . 6. Simultaneous use of the additive with 25-hydroxycholecalciferol shall not be permitted. 7. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the potential risks	

<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> 40 IU cholecalciferol (vitamin D<sub>3</sub>)= 0,001 mg cholecalciferol (vitamin D<sub>3</sub>).

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<b>Category of nutritional additives. Functional group: vitamins, pro-vitamins and chemically well-defined substances having similar effect. Subclassification: Vitamin D</b>								
							resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing and skin protective equipment.	