



ORFFA

CALSPORIN®

Name change for Calsporin® is official! From *Bacillus subtilis* to *Bacillus velezensis*

Renewal and amendments of Calsporin® authorisations

On May 5th, 2022, [Commission implementing regulation \(EU\) 2022/703](#) was published in the EU official journal (OJ).

With this legislation, the **authorisation** of Calsporin® as gut flora stabiliser is renewed **for weaned piglets and for all avian species and categories**, both with a minimum content of 3×10^8 CFU/kg feed. Additionally, the name of the microbial strain used in the Calsporin® changes for all authorised animal species.

Reclassification of Calsporin®

During evaluation of the EFSA panel of experts, examining the efficacy and safety of feed additives for these renewals, it was concluded that the bacterial strain used in the Calsporin®, formerly known as *Bacillus subtilis* C-3102 (DSM 15544), should be reclassified as *Bacillus velezensis* DSM 15544. This was published in the EFSA Scientific Opinions on Calsporin® from end 2020 onwards.

As a product with two different microbial names on the label is confusing and not feasible, it was necessary to change also the other existing authorisations for Calsporin®. This uniformization required some bureaucracy and time.

Legal finalization of the name change

Together with the official publication of the renewals, also the other existing authorisations for Calsporin® are amended. This results in the official replacement of *Bacillus subtilis* C-3102 (DSM 15544) into *Bacillus velezensis* DSM 15544 for all the animal species with an authorisation. By this change, the name of the probiotic strain in Calsporin® is in accordance with the latest taxonomical identification and newest genetic insights.

After publication of Regulation (EU) 2022/703, also the European feed additive register will be adjusted accordingly. Thereafter, Calsporin®, with its new name *Bacillus velezensis*, can still be found in the list as a zootechnical additive in the functional group of gut flora stabilisers with EU identification number 4b1820.

DSM number explained

The specific probiotic strain used in Calsporin® is included in the German Collection of Microorganisms and Cell Cultures (DSMZ) with the accession number DSM 15544. As, although the name change, the strain stays the same, this number will not change and will always be the active agent in the additive Calsporin®.

Consequences for feed labels

If a feed (complete or complementary) contains Calsporin®, this should be mentioned under 'additives' on the label. For food-producing animals, this includes the specific name, the amount, the identification number and the name of the functional group. **It will be necessary to adjust the specific name on the label into *Bacillus velezensis* DSM 15544.** For non-food producing animals, the specific name and/or its identification number, the amount and the name of the functional group should be mentioned on the label. Also here, if the label contained previously *Bacillus subtilis* C-3102 (DSM 15544), this should either be removed (in case the identification number 4b1820 is mentioned) or replaced by *Bacillus velezensis* DSM 15544.

Transitional arrangements

The regulation (EU) 2022/307 enters into force on the twentieth day following its publication in the OJ. Therefore, from 26/05/2022 onwards, the new name *Bacillus velezensis* can be mentioned on the label.

To allow a feasible transition to the new legislation, transitional arrangements are applied for labelling and stocks. All labels should be adjusted by the end of the transition period, which depends on the type of product as shown in table 1. Products produced and labelled before that date, can be sold until stocks are used up.

Table 1: transitional period

Products containing Calsporin®	Transition period	Stocks can be sold of products produced and labelled before
Calsporin® (as additive) and premixtures	6 months	26/11/2022
Feed for food-producing animals	12 months	26/05/2023
Feed for non-food producing animals	24 months	26/05/2024



Calsporin® officially becomes *Bacillus velezensis* DSM 15544



Same strain, it is only the name



Adjustment of your labels is required



Broad range of authorisations

For more information please visit our website (www.orffa.com) and contact one of our specialists.

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