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Safety and efficacy of 036 10 (*Bacillus subtilis* DSM 27273) as a feed additive for weaned piglets and minor porcine species

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP)

Abstract

The additive 036 10 contains viable spores of a strain of *Bacillus subtilis*. The bacterial species *B. subtilis* is considered by EFSA to be suitable for the qualified presumption of safety approach to safety assessment. As the identity of the active agent has been established and the susceptibility to antibiotics and lack of toxigenic potential have been demonstrated, the use of the additive can be presumed safe for the target species for which an authorisation is being sought. The dustiness of the 036 10 indicated a potential for users to be exposed via inhalation. Given the proteinaceous nature of the active agent, the additive should be considered to have the potential to be a respiratory sensitiser and treated accordingly. In the absence of data, the Panel on Additives and Products or Substances used in Animal Feed cannot conclude on the ocular and dermal irritancy of the additive or its dermal sensitisation. Evidence has been provided that 036 10 has a potential to improve at least one zootechnical parameter when fed to weaned piglets at the minimum proposed dose of 4×10^8 CFU/kg complete feedingstuffs. Since the efficacy of 036 10 for weaned piglets has been established, the product can be assumed to be efficacious for weaned minor porcine species at the same dose.

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Keywords: zootechnical additive, 036 10, *Bacillus subtilis*, safety, efficacy, piglets and minor porcine species

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Note: The full opinion will be published in accordance with Article 8(6) of Regulation (EC) No 1831/2003 once the decision on confidentiality, in line with Article 18(2) of the Regulation, will be received from the European Commission.

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Summary

Following a request from the European Commission, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) was asked to deliver a scientific opinion on the safety and efficacy of 036 10 when used in feed for weaned piglets and weaned minor porcine species at a minimum dose of 4×10^8 colony-forming units (CFU)/kg complete feedingstuffs. The additive is a preparation containing viable spores of a strain of *Bacillus subtilis*.

The bacterial species *B. subtilis* is considered by the European Food Safety Authority to be suitable for the qualified presumption of safety approach to safety assessment. As the identity of the active agent has been established and the susceptibility to antibiotics and lack of toxigenic potential have been demonstrated, the use of 036 10 can be presumed safe for the target species for which an authorisation is being sought.

The dustiness of the additive indicated a potential for users to be exposed via inhalation. Given the proteinaceous nature of the active agent, the additive should be considered to have the potential to be a respiratory sensitiser and treated accordingly. In the absence of data, the FEEDAP Panel cannot conclude on the irritancy of the additive to skin and eyes or its dermal sensitisation.

Evidence has been provided that the additive has a potential to improve at least one zootechnical parameter when fed to weaned piglets at the minimum proposed dose of 4×10^8 CFU/kg complete feedingstuffs. Since the efficacy for weaned piglets at 4×10^8 CFU/kg complete feedingstuffs has been established, the product can be assumed to be efficacious for weaned minor porcine species at the same dose.