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Safety of Lancer (lanthanide citrate) as a zootechnical additive for weaned piglets

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

Abstract

Lancer (lanthanide citrate) is a feed additive mainly consisting of two rare earth elements, lanthanum (La) and cerium (Ce), in their citrate forms. Lancer has not been previously authorised in the European Union. In 2013, the EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) issued an opinion on the safety and efficacy of Lancer as a zootechnical feed additive for weaned piglets. In its opinion the FEEDAP Panel could not conclude on the safety of the additive for the target species, on the safety for the consumer and on the safety for the environment. As a result of the additional information provided by the applicant, the FEEDAP Panel concluded that the additive Lancer is safe for weaned piglets when used at the maximum recommended dose of 250 mg/kg complete feed. In view of concerns over the possible developmental neurotoxicity of La, the many gaps in the available toxicological information on Ce and La, the absence of studies of long-term toxicity, carcinogenicity, reproductive toxicity and developmental toxicity of Lancer, and the absence of residue data in edible tissues, the FEEDAP Panel cannot conclude on the safety of Lancer for the consumer. In the absence of adequate data the FEEDAP Panel cannot conclude on the safety of Lancer for the environment.

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Keywords: Lancer, lanthanide citrate, zootechnical additive, weaned piglets, safety

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Note: The full opinion will be published in accordance with the applicable provisions on confidentiality.

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Summary

Following a request from the European Commission, the EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) was asked to deliver a scientific opinion on the safety of Lancer (lanthanide citrate) as a zootechnical additive (other zootechnical additives) for weaned piglets.

Lancer is a feed additive mainly consisting of two rare earth elements, lanthanum (La) and cerium (Ce), in their citrate forms. Lancer has not been previously authorised in the European Union.

In 2013, the FEEDAP Panel issued an opinion on the safety and efficacy of the additive. In that opinion, the FEEDAP Panel could not conclude on the safety of the additive for the target species because of serious flaws found in the tolerance studies provided. The Panel did not conclude on consumer safety as a no observed adverse effect level (NOAEL) could not be set and it could not be excluded that there would be consumer exposure to residues derived from the additive. Finally, in the absence of data on the toxicity of the additive to terrestrial organisms in the environment, a full environmental assessment could not be completed.

The applicant submitted additional information related to the safety of the additive for the target species, the consumer and the environment and this new information is the subject of this opinion.

The FEEDAP Panel concluded that the additive Lancer is safe for weaned piglets when used at the maximum recommended dose of 250 mg/kg complete feed.

As no new information is available to indicate the extent to which ingested Lancer and its component chemicals may be absorbed from the gastrointestinal tract, may accumulate in the body or leave residues in edible tissues of the target animals, the level of exposure of consumers is still not known.

In the re-evaluation of the results of the 90-day rat toxicity study, a no observed effect level (NOEL) of 300 mg/kg bw day was identified for forestomach hyperplasia. This lesion was considered of no relevance for consumer safety.

In view of concerns over the possible developmental neurotoxicity of La, the many gaps in the available toxicological information on Ce and La, the absence of studies of long-term toxicity, carcinogenicity, reproductive toxicity and developmental toxicity of Lancer, and the absence of residue data in edible tissues, the FEEDAP Panel cannot conclude on the safety of Lancer for the consumer.

Information needed for the assessment of the exposure of the soil to La and Ce and adequate data on plant and earthworm ecotoxicity has not been provided. Predicted environmental concentration (PEC) and predicted no effect concentration (PNEC) values have not been provided and therefore, no risk quotient can be determined. Consequently, in the absence of adequate data, the FEEDAP Panel cannot conclude on the safety of Lancer for the environment.