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Safety and efficacy of methylester of conjugated linoleic acid (t10,c12 isomer) for pigs for fattening, sows and cows

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

Abstract

A mixture of methylated (ME) conjugated linoleic acid (CLA) isomers (t10,c12 and c9,t11) in equal proportions was not genotoxic and caused no reproductive toxicity. In a sub-acute study in dogs, a sub-chronic toxicity study in rats and a chronic study in dogs, no adverse effects were seen up to the highest levels tested. The maximum recommended feed concentration (5 g CLA (t10,c12)-ME from Lutalin®/kg feed for piglets, pigs for fattening and sows) or dose (30 g CLA (t10,c12)-ME from Lutrell® Pure/cow per day) is considered safe for target species. The CLA content of milk from cows treated with the highest recommended dose did not exceed background values (in milk of untreated cows) for both CLA isomers. An estimate of consumer exposure to both CLA isomers from food from pigs receiving 3 g of both CLA isomers/kg feed is ≤ 320 mg CLA isomers/person and day. This quantity corresponds to about 9% of the quantity considered safe for 6 months and is considered unlikely to raise concerns for consumer safety. Exposure of users by inhalation of the additive is likely to be minimal. Neither of the products under application, the liquid or the solid product, was tested as such for skin and eye irritation and skin sensitisation. The use of the additive in animal nutrition would not pose a risk to the environment. In pigs for fattening, CLA (t10,c12)-ME has a potential for improving feed to gain ratio. More consistent effects are a reduction in subcutaneous fat, an increase in intramuscular fat and fat firmness. No essential effects were found in sows. Administration of CLA to dairy cows reduces in a dose-dependent manner the fat content of milk, and milk fat yield. Energy balance in early lactation is improved by CLA (t10,c12)-ME; however, reproductive parameters were not influenced.

Keywords: nutritional additives, conjugated linoleic acid methylester, CLA (t10,c12) isomer, cows, pigs

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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 omega-6-fatty acid as octadecadienoic acid (conjugated linoleic acid (CLA)-methylester) as a nutritional additive for pigs and cows (dairy and beef cows).

The active substance under assessment is methylated CLA trans10,cis12-C18:2 isomer (CLA (t10,c12)-ME). It is contained in two different additives together with an approximately equal proportion of methylated CLA cis9,trans11-C18:2 isomer (CLA (c9,t11)-ME).

A mixture of methylated CLA isomers (t10,c12 and c9,t11) in equal proportions was not genotoxic and caused no reproductive toxicity. In a sub-acute study in dogs, a sub-chronic toxicity study in rats and a chronic study in dogs, no adverse effects were seen up to the highest levels of methylated CLA isomers tested (180, 390, and 430 mg CLA (t10,c12)-ME/kg bw per day, respectively).

The maximum recommended feed concentration/daily dose of CLA (t10,c12)-ME is considered safe for all target species. This concentration for piglets, pigs for fattening and sows is 5 g CLA (t10,c12)-ME from Lutalin®/kg feed (corresponding to 17 g Lutalin®/kg feed), the daily dose for dairy cows is 30 g CLA (t10,c12)-ME from Lutrell® Pure/cow per day (corresponding to 300 g Lutrell® Pure/cow per day). A margin of safety could not be determined for any target animal.

The quantity of both CLA isomers which was considered safe by the NDA Panel is 3.5 g/adult and day for a period of 6 months. No data for chronic exposure were available. The CLA content of milk from cows treated with the highest recommended dose (≤ 30 g CLA (t10,c12)-ME from Lutrell® Pure/cow and day) did not exceed background values (in milk of untreated cows) for both CLA isomers. Consequently, there is no concern for the safety of persons consuming milk from treated cows up to the maximum proposed dose.

An estimate of consumer exposure to both CLA isomers from food from pigs receiving 3 g of both CLA isomers/kg feed is ≤ 320 mg CLA isomers/person and day. This quantity corresponds to about 9% of the quantity considered safe by the NDA Panel for 6 months. This level of exposure can only be ensured if 5 g Lutalin®/kg feed in pigs (3 g CLA (t10, c12 + c9,t11)/kg feed) would not be exceeded. Considering (i) the large variation of measured CLA tissue concentrations, particularly in subcutaneous fat, (ii) the remaining uncertainties leading to an overestimate of the intake, and (iii) the variability of additional exposure from other sources depending on dietary factors, this level is unlikely to raise concerns for consumer safety.

Exposure of users by inhalation of the solid product is likely to be minimal. Neither of the products under application, the liquid or the solid product, was tested as such for skin and eye irritation and skin sensitisation.

The use of CLA (t10,c12)-ME in animal nutrition would not increase CLA concentration in the environment and is therefore without concern for the environment.

In pigs for fattening, no increase in daily gain or feed consumption can be expected; however, there might be a potential for an improvement in feed to gain ratio at dietary levels at about 1.5 g CLA (t10,c12)-ME/kg feed or higher. More consistent effects can be expected at lower feed concentrations (from 0.2 to 0.4 g CLA (t10,c12)-ME/kg on upwards) on a reduction in subcutaneous fat in the carcass, an increase in intramuscular fat and fat firmness. CLA does not positively affect energy balance of sows and their fertility. The number of piglets and their performance are also not influenced by CLA feeding to sows.

Administration of CLA to dairy cows reduces the fat content of milk; milk fat yield is reduced to a lesser degree as milk yield shows a tendency to increase. This effect is dose dependent, the lowest efficacious dose being 6 g CLA (t10,c12) from Lutrell® Pure per cow and day. Energy balance (body weight loss) in early lactation is improved by feeding CLA as a consequence of reduced milk fat synthesis. To obtain consistent effects, higher doses (> 6.1 g per cow and day) than for reduced milk fat appear necessary. Reproductive parameters were not influenced.

The FEEDAP Panel made recommendations on the description of the active substance.