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Safety and efficacy of polyoxyethylene (20) sorbitan monooleate as a feed additive for all animal species

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

Abstract

The additive is a mixture of the partial esters of sorbitol and its mono- and dianhydrides with edible commercial oleic acid and condensed with approximately 20 moles of ethylene oxide per mole of sorbitol and its anhydrides. It contains a minimum of 65% of oxyethylene groups, equivalent to not less than 96.5% of polyoxyethylene (20) sorbitan monooleate on the anhydrous basis and less than 3% water. The following concentrations of polyoxyethylene (20) sorbitan monooleate per kg complete feedingstuffs are considered safe: 1,260 mg for salmonids, 1,100 mg for cattle for fattening, 830 mg for pigs for fattening and sows, 750 mg for turkeys for fattening, 720 mg for dairy cows, 500 mg for piglets, 420 mg for chickens for fattening and laying hens, 1,320 mg for dogs and 1,100 mg for cats; and 5,000 mg/kg milk replacer are considered safe for calves. The use of polyoxyethylene (20) sorbitan monooleate as feed additive for all animal species at the maximum concentration proposed of 5,000 mg/kg complete feedingstuffs would not raise concerns for the consumer. Polyoxyethylene (20) sorbitan monooleate is non-irritant to skin and eyes, and is not a skin sensitiser. There is evidence that dermal or oral exposure to the additive can exacerbate the symptoms in individuals who are already sensitised. Users are unlikely to be exposed to the additive by inhalation. The lack of data and the inherent uncertainties do not allow concluding on the safety for the environment. Polyoxyethylene (20) sorbitan monooleate is a recognised emulsifier used in food and it is expected to have the same effect when applied to feed. From the practical examples provided, polyoxyethylene (20) sorbitan monooleate appears to be effective in aiding and maintaining the homogeneous distribution of feed materials and/or additives in feedingstuffs.

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Keywords: polyoxyethylene (20) sorbitan monooleate, safety, efficacy, technological additive, emulsifier, target species

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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 polyoxyethylene (20) sorbitan monooleate when used in feedingstuffs for all animal species.

The additive is a mixture of the partial esters of sorbitol and its mono- and dianhydrides with edible commercial oleic acid and condensed with approximately 20 moles of ethylene oxide per mole of sorbitol and its anhydrides. It contains a minimum of 65% of oxyethylene groups, equivalent to not less than 96.5% of polyoxyethylene (20) sorbitan monooleate on the anhydrous basis and less than 3% water.

The following concentrations of polyoxyethylene (20) sorbitan monooleate per kg complete feedingstuffs are considered safe: 1,260 mg for salmonids, 1,100 mg for cattle for fattening, 830 mg for pigs for fattening and sows, 750 mg for turkeys for fattening, 720 mg for dairy cows, 500 mg for piglets, 420 mg for chickens for fattening and laying hens, 1,320 mg for dogs and 1,100 mg for cats; and 5,000 mg/kg milk replacer are considered safe for calves.

The use of polyoxyethylene (20) sorbitan monooleate as feed additive for all animal species at the maximum concentration proposed of 5,000 mg/kg complete feedingstuffs would not raise concerns for the consumer.

Polyoxyethylene (20) sorbitan monooleate is non-irritant to skin and eyes, and is not a skin sensitiser. There is evidence that dermal or oral exposure to the additive can exacerbate the symptoms in individuals who are already sensitised. Users are unlikely to be exposed to the additive by inhalation.

The lack of data and the inherent uncertainties do not allow concluding on the safety for the environment.

Polyoxyethylene (20) sorbitan monooleate is a recognised emulsifier used in food and it is expected to have the same effect when applied to feed. From the practical examples provided, polyoxyethylene (20) sorbitan monooleate appears to be effective in aiding and maintaining the homogeneous distribution of feed materials and/or additives in feedingstuffs.