

Outcome of assessment of 3-Nitrooxypropanol “3-NOP” - Conclusions

The additive was fully characterised in the application and no causes for concern were identified by the AFFAJEG in the identity and characterisation.

The AFFAJEG concluded that the additive can be considered safe for the target species at a maximum dose of 200 mg/kg DM (176 mg/kg in complete feed), establishing a margin of tolerance of 2. An ADI of 0.3 mg/kg bw was established. Metabolism of 3-NOP produces 1,3 - propanediol in the rumen. Propanediol does not accumulate in the rumen and is no cause for concern. Concentrations of 3-NOP and its metabolites in milk and edible tissues are not expected to reach levels of concern. The additive should be considered corrosive to the eyes, a skin irritant and potentially harmful by inhalation; it is not a skin sensitizer. It was concluded the additive poses an acceptable risk to the environment.

Based on data from in-vitro studies, two meta-analysis and three long-term efficacy trials, the AFFAJEG concluded that the product can be considered efficacious for reducing methane production in ruminants when fed daily at the proposed dose of 52.8 - 88 mg/kg of complete feed.