



KemTRACE® Chromium for Horses and the Amended Food Additive Regulation with the U.S. Food and Drug Administration

What is chromium and why should I feed it?

Chromium is a trace mineral that helps improve glucose utilization for increased cellular energy and function. This results in better animal maintenance, growth, health and performance. Chromium accomplishes this by optimizing insulin receptors on the cell allowing for increased glucose uptake. KemTRACE Chromium supplies chromium to the diet in the form of chromium propionate.

What is a Food Additive Petition (FAP) and what does a FAP approval mean?

The FDA's Center for Veterinary Medicine (CVM) is responsible for the regulation of animal food (feed) products. A manufacturer or other sponsor may petition the FDA for approval of a new animal food additive or they may petition for a new use of an already approved animal food additive. The FAP process will review the additive's:

- identify and chemical structure
- efficacy
- safety
- manufacturing chemistry
- analytical methods for testing
- stability
- mixing and homogeneity
- environmental assessment
- labeling

Once approved, the product can be used as indicated in the regulation. Additionally, if any competitive form of the approved product enters the market, it is required to meet all specifications listed in the regulation.

Can KemTRACE Chromium be used in both horse feed and supplements?

The FDA regulates ingredients for animal feed, of which ingredients for supplements are included. Chromium propionate has been approved by the FDA for its use in horse diets. KemTRACE Chromium is currently the only FDA-reviewed source of chromium propionate on the market.

How does the chromium propionate in KemTRACE Chromium differ other sources of chromium?

The specifications for the chromium propionate in KemTRACE Chromium includes a description of how the chromium propionate must be manufactured, as well as the specific chemical identity and structure of the molecule to ensure safety and efficacy. In addition, limits for heavy metals and other impurities are clearly defined. Therefore, the structure, consistency and safety of KemTRACE Chromium are thoroughly understood.

What safety data does Kemin have concerning the use of KemTRACE Chromium in horses?

Data was generated to support safe use of chromium propionate in horses as well as environmental safety data.

Chromium propionate was fed to horses using KemTRACE Chromium at the recommended feeding levels and at rates that were significantly higher than the recommended feeding levels. Animal performance and blood chemistry was monitored, with no negative effects identified.

Kemin completed an environmental safety assessment that described the proposed use of the product, its expected fate in the environment and the predicted environmental concentration of chromium propionate in the soil. Upon review of the assessment, FDA issued a Finding of No Significant Impact (FONSI), confirming no significant impacts are expected from the proposed use of chromium propionate in horses as a supplemental source of chromium.



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What is the recommended feeding level for KemTRACE Chromium?

Feed 1g/h/d of KemTRACE Chromium 0.4% to deliver 4 mg of chromium/h/d.

Feed 10g/h/d of KemTRACE Chromium 0.04% to deliver 4 mg of chromium/h/d.

Chromium from all sources of supplemental chromium cannot exceed 4 mg/h/d, therefore KemTRACE Chromium should be formulated to the highest suggested feeding rate for your feed or supplement.

Is there any additional information that needs to be included on the labels of feed and supplements that contains KemTRACE Chromium?

All labels of the feed, premix or supplements should contain the name chromium propionate in the ingredient listing. In addition, all industry and regulatory guidelines need to be met.

In what other countries can KemTRACE Chromium be used in horse feed and supplements?

KemTRACE Chromium is available for use in horse feed and supplements in Mexico. Additionally, KemTRACE Chromium is available for use in more than 35 countries around the world. Approved use by species varies from country to country.

Contact your Kemin representative concerning any questions or inquiries.

References

1. 21 CFR Part 573.304, Chromium Propionate.