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FINDING OF NO SIGNIFICANT IMPACT

for
RUMEN PROTECTED AMINO ACID

for
BEEF CATTLE

Food Additive Petition Number 2197

Eastman Kodak Company
Eastman Chemical Division
Kingsport, Tennessee

The Center for Veterinary Medicine has carefully considered the potential environmental impact of this action and has concluded that this action is not expected to have a significant impact on the quality of the human environment and that an environmental impact statement therefore will not be prepared.

Eastman Kodak Company, Kingsport, Tennessee is requesting the approval of FAP 2297 for the use of rumen protected amino acids (RPAA) for beef cattle in feedlots and farmer-feeder operations. RPAA is in a form that will protect the amino acids (methionine and lysine) from destruction in the rumen and release the nutrients for absorption. The protecting component of the RPAA (copoly VP/ST) is then released unchanged into the environment. In support of this requested approval, Kodak has provided the attached May 14, 1990, environmental assessment (EA).

The EA was placed on display in the Food and Drug Administration Dockets Management Branch for 30 days and its availability was advertised in the October 31, 1991, FEDERAL REGISTER Notice. The comment period closed on December 2, 1991. No comments were received

Information in the EA indicates that RPAA consists of lysine, methionine stearic acid, talc and copoly VP/ST. Copoly VP/ST is produced at Arkansas Eastman Company, Batesville, Arkansas. The final RPAA product is produced at Tennessee Eastman Company in Kingsport, Tennessee. Information in the EA indicates that employees at these facilities are provided with the necessary safety information and that the facilities are in compliance with the appropriate Federal, State and local environmental requirements. Therefore, no significant impacts to the environment are expected at the sites of manufacture.

Information in the EA indicates that three of the five components of RPAA, lysine, methionine and talc, are naturally occurring products. A fourth component, stearic acid, is a edible fatty acid. Because of the nature of the compounds, the EA only addresses them to a limited, but sufficient, extent to

determine that they will not contribute to the potential for the product to have a significant impact in the environment. The component most prominently covered in the EA is the copoly VP/ST.

Copoly VP/ST is expected to enter the environment through the manure at appreciable levels. Although the EA indicates that the amount that is expected to enter the environment is 1.17 ppm, the correct calculated value is 1.13 ppm. To address the potential for copoly VP/ST to have impact in the environment, Kodak undertook numerous studies to estimate its environmental fate and potential effects. The data in the EA indicate that copoly VP/ST will enter terrestrial environment through manure and that it will subsequently bind to soils. This binding is expected to eliminate the potential for copoly VP/ST to move into aquatic environment. Data in the EA also indicate that no degradation through physical or biological means are expected to occur. Therefore, effects data were determined for terrestrial species. In particular, Kodak has conducted two seedling growth tests and a dungworm toxicity test with copoly VP/ST.

The first seedling growth test found statistically significant adverse dose related trends in corn and soybean plant height and lettuce root length. Although a trend was reported, no significant effects in individual parameters when compared to controls were observed, even at 1000 ppm. However, because of the trend and questions concerning the biological significance of the trend, a follow-up seedling growth study was conducted. This study was designed to be more powerful than the previous study and, although there are statistical errors, as reported in the attached Statistical Appendix, the study accomplished this goal.

The follow-up seedling growth study did not show the same effects as the first study and, in particular, the adverse dose related trends in corn and soybean plant height and lettuce root length, observed in the first study, were not observed. There is an adverse effect reported on elongation percentages for corn at 1000 ppm. However, this effect is different than the effect observed in the first study and corresponding effects in the actual height data for corn, that are used to calculate the elongation percentage, were not observed. Therefore, the biological significance of this effect is questionable. Given the lack of repeatable effects, the high concentrations at which any effects are observed and the questionable biological significance of the effect on corn elongation percentage, the data indicate that, at the level of introduction, no significant effects from copoly VP/ST would be expected in plants.

The dungworm study was conducted in 1985 and there were significant procedural difficulties with the study. Although there were sublethal effects reported in the study associated with the flaccidity of the worms, no significant dose related mortalities were observed and the information presented in the study indicates that copoly VP/ST does not appear to be very acutely toxic to the species of worm tested. Based upon this information, copoly VP/ST is not expected to have any significant acute toxic effects to dungworms. As this species is considered to be representative of terrestrial invertebrates, these data indicate that copoly VP/ST would not have a significant impact on these organisms.

Based upon the information provided in the EA, the Center concludes that copoly VP/ST and, consequently, RPAA is not expected to have a significant impact on the environment.

12/13/91
Date

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Attachments

June 13, 1991, Statistical Appendix

May 14, 1990, Environmental Assessment Vol. I - II