



## Generally Recognized as Safe (GRAS) Determination for:

### **Intentional use of Lactoside 247™ as a processing aid in renewable fuel production Distillers' grains containing Virginiamycin residues of 1 PPM are considered safe**

Lallemand Biofuels & Distilled Spirits has successfully completed a review for **Lactoside 247™**, resulting in a GRAS (Generally Recognized as Safe) determination as defined by Section 201(s) of the Federal Food, Drug and Cosmetic Act and corresponding Food and Drug Administration (FDA) guidelines. Penicillin and virginiamycin are the active ingredients in **Lactoside 247™**, a leading antimicrobial for renewable fuels and distillers' grain production.

Lallemand Biofuels & Distilled Spirits has consistently been working on regulatory compliance for all its antimicrobial products with the FDA. A number of years ago, under the guidance of the FDA's Food Additive Petition (FAP) process, Lallemand Biofuels & Distilled Spirits began preparing scientific data and research necessary to secure long-term regulatory compliance for **Lactoside 247™**. During this time, Lallemand Biofuels & Distilled Spirits developed a proprietary process for determination of residuals in distillers' grains.

Since its launch, **Lactoside 247™** has proven to be a safe product for use in renewable fuels and distillers' grain production. The GRAS determination was made by independent experts and counsel after a comprehensive evaluation of Lallemand Biofuels & Distilled Spirits' validated residual test method and scientific data.

The experts' determination was based upon the publicly available scientific literature pertaining to the safety of the product, the demonstrated absence of penicillin residues in the finished feed ingredient (distillers' grain) and a dietary exposure assessment which concludes that virginiamycin residues of 1 ppm in distillers' grain are recognized as safe. Typical virginiamycin residues associated with the use of **Lactoside 247™** are significantly lower.

The **Lactoside 247™** GRAS determination achieves full regulatory compliance and obviates the need for a Food Additive Petition. However, Lallemand Biofuels & Distilled Spirits is committed to working with FDA and will submit its scientific data and research to CVM for the record.