



---

Corporate Office: N8790 Fairground Avenue, P.O. Box 160 • Greenwood, WI 54437-0160 • Phone (715) 267-6182 • Fax (715) 267-6044

### **GRAS Statement**

"GRAS" is an acronym for the phrase **Generally Recognized As Safe**. Under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act (the Act), any substance that is intentionally added to food is a food additive, that is subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise exempted from the definition of a food additive.

Under sections 201(s) and 409 of the Act, and FDA's implementing regulations in 21 CFR 170.3 and 21 CFR 170.30, the use of a food substance may be GRAS either through scientific procedures or, for a substance used in food before 1958, through experience based on common use in food. Under 21 CFR 170.30(b), general recognition of safety through scientific procedures requires the same quantity and quality of scientific evidence as is required to obtain approval of the substance as a food additive.<sup>1</sup>

Milk products meet this category requirement, therefore the status does not need affirmation by the FDA.

Laura J. Opelt  
Corporate Manager  
Grassland Dairy Products, Inc.  
West Point Dairy Products, LLC (also d/b/a Alcam Creamery)  
Graf Creamery, Inc.  
June 5, 2019

---

<sup>1</sup> <https://www.fda.gov/food/ingredientpackaginglabeling/gras/>