

July 10, 2025

Generally Recognized As Safe Conclusion

US law and regulation stipulate that food ingredients are either food additives or Generally Recognized As safe substances¹. Determining the Generally Recognized As Safe (GRAS) status of a product is the responsibility of the manufacturer or seller of the food. A manufacturer or seller that makes a GRAS determination may or may not notify FDA as to the GRAS status of the ingredient, as notification of FDA is optional at the manufacturers' discretion.

In compliance with US law and regulation^{2,3}, Verb Biotics, LLC has determined, by scientific procedures, **assessment by a third party panel of experts in the field**, and history of common use in food prior to January 1, 1958 that *L. plantarum* 815 (LP815®) is Generally Recognized As Safe (GRAS) for general use in foods as a food ingredient as all components of the product have a safe history of use in food; and/or are GRAS substances or approved food additives in the US and is manufactured in accordance with cGMP for food ingredients as stipulated in 21 CFR part 117. As *L. plantarum* 815 (LP815®) is GRAS under the conditions of its intended use, it is not a "food additive" and is therefore not subject to mandatory premarket review by FDA under section 409 of the FD&C Act.

A copy of the self-affirmed dossier can be provided upon request under, with a signed NDA.

This GRAS statement applies to the following: ***L. plantarum* 815 (LP815®)**

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¹ Section 409 of the Food Drug and Cosmetic Act (FD&C Act)

² Section 201(s) of the FD&C Act

³ 21 CFR part 170