



January 1, 2024

Dear valued Primient Customer,

Thank you for your inquiry on the Ready to Eat status of Primient products.

**Per United States Code of Federal Regulations 21 CFR 117.3,**

***“Ready-to-eat food (RTE food) means any food that is normally eaten in its raw state or any other food, including a processed food, for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards.”***

**21 CFR PART 117**

**CURRENT GOOD MANUFACTURING PRACTICE,**

**HAZARD ANALYSIS, AND**

**RISK-BASED PREVENTIVE CONTROLS FOR HUMAN FOOD**

Our products might require further processing, depending on our customer's end use; however, the purpose is not to minimize or eliminate biological hazards.

Our manufacturing facilities are GFSI certified, and each process is controlled with a FSMA compliant HACCP program. Our HACCP programs have not identified any kill steps as a process control requirement for the production process. Even so, processing conditions involve temperatures greater than 60-90°C. In addition, our acidulant products have water activity below 0.5, some as low as 0.15. Our acidulant products are also protected from microbiological concerns due to their low pH (<2.5). Lethality treatment validation data is not available.

The quality of our finished products is of utmost importance and priority to Primient. We understand our customers' need for high quality and reliable ingredients. Your business is important to us. If you have any questions or require further information, please contact us.

Sincerely,

Victoria Alao  
Product Regulatory Manager  
Primary Products Ingredients Americas LLC.

References:

- 1) CRA. Food Safety Information Papers-Microbial Assesment-5. Available from: <https://corn.org/wp-content/uploads/2009/12/pathogens2013.pdf> Retrieved: April/2020
- 2) United States Code of Federal Regulations 21 CFR 117.3  
[CFR - Code of Federal Regulations Title 21 \(fda.gov\)](https://www.ecfr.gov/current/title-21-chapter-I-subchapter-B-part-117-subpart-A)

Primient is providing the data contained in this letter in good faith for your information only. The data is based on available information in our possession as at the date of this letter. Prospective purchasers are advised to conduct their own tests, studies, and regulatory review to determine the fitness of Primient products for their particular purposes, product claims, or specific applications.