Purium Biome Medic Gluten Analysis Prepared by: Research and Development 08/23/2017 Internal use only

Introduction

The scope of this analysis is to determine if Purium's Biome Medic product will have any adverse affect on persons with celiac disease (CD). In a study published in the American Society for Clinical Nutrition¹, 50 persons with CD were exposed to various levels of gluten. The study concluded that the ingestion of gluten should be kept lower that 50mg/day in the treatment of CD.

Gluten exposure calculation for 'Gluten-Free' Pasta

- Standard recommended servings size for Gluten Free Pasta is 56g (56000mg)
- FDA limit to claim gluten free is 20ppm (20mg gluten / 1kg of food)

Calculation for Gluten exposure per serving is as follows;

$$56g Pasta \times \frac{1kg}{1000g} = .056kg Pasta$$

Assuming 20 ppm (FDA limit)

 $0.056 \frac{kg \ pasta}{1 \ kg \ pasta} \times \frac{20 mg \ gluten}{1 \ kg \ pasta} = \frac{1.12 \ mg \ gluten \ per \ serving}{1.12 \ mg \ gluten \ per \ serving}$

Gluten exposure calculation for Purium's Biome Medic

- Serving size is 1 capsule (550mg)
- Gluten testing indicates 218ppm

Calculation for Gluten exposure per serving is as follows

$$550 \frac{1g}{mg}$$
 Biome Medic $\times \frac{1g}{1000 \frac{mg}{mg}} \times \frac{1kg}{1000 \frac{g}{g}} = .00055 kg$ Biome Medic

Using test result of 218ppm

 $0.00055 \frac{kg Biome Medic}{1 \frac{kg Biome Medic$

Conclusion

One would have to ingest almost 10 pills per day to be exposed to the same amount of gluten contained in a single serving of gluten free pasta, and over 500 pills to reach the threshold established in the American Society for Clinical Nutrition study from 2007.

¹<u>http://ajcn.nutrition.org/content/85/1/160.full</u>