



Safety assesment of *Bacillus clausii* UBBC07, a spore forming probiotic

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Summary :

Probiotics are vital bacteria that colonize the intestine and modify its microflora with benefits for the host. Very few members of the *Bacillus* group are recognized as safe for use and hence only a few strains are available as commercial preparations for application in humans and animals. Acute and subacute studies in rats were conducted to establish safety of *Bacillus clausii* (*B. clausii*) UBBC07. In the acute toxicity study, the oral LD50 for *B. clausii* UBBC07 was found to be >5000 mg/kg (630 billion cfu/kg) body weight. The NOAEL for *B. clausii* UBBC07 was found to be 1000 (126 billion cfu) mg/kg body weight/day by oral route in the subacute toxicity study. There were no significant differences between control and treated groups in any of the endpoints assessed using an OECD443 or OECD407 protocol. *B. clausii* UBBC07 was found to be resistant to three antibiotics -clindamycin, erythromycin and chloramphenicol. Analysis of the whole genome sequence of *B. clausii* UBBC07 revealed that the antibiotic resistance genes are present in chromosomal DNA which is intrinsic and not transferable. Toxin genes were also found to be absent. These results suggest consumption of *B. clausii* UBBC07 is safe for humans.
