

Summary of the application: Phosphopropylsilanetriol stabilized on lactose – PPST-L

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This is an application for a new form of silicon intake – organic and bioavailable – (hereinafter referred to as Phosphopropylsilanetriol stabilized on lactose – PPST-L) under the novel food Regulation (EU) 2015/2283.

Phosphopropylsilanetriol stabilized on lactose – PPST-L is an oligomeric mixture of per-diethyl-phosphate-ethyl-oligosil-sesquioxanols adsorbed on lactose monohydrate. This novel food falls under the categories (i) of Article 3 of Regulation (EU) No 2015/2283: “food with a new or intentionally modified molecular structure, where that structure was not used as, or in, a food within the Union before 15 May 1997”.

Phosphopropylsilanetriol stabilized on lactose – PPST-L contains between 16.0% and 20.0% of oligosilsesquioxane mixture and between 80.0% and 84.0% of lactose monohydrate. Lactose monohydrate is made from whey from bovine milk in compliance with the current European Pharmacopoeia (Ph. Eur.). Product specifications for characterisation of the novel food: identity, production process, compositional data and potential contaminants have been established for this novel food. The results of batch analyses indicate that the manufacturing process produces a consistent product meeting the product specifications. Analysis also demonstrates that heavy metal and microbial are below norms for microbial. Furthermore, the results of stability studies indicate that Phosphopropylsilanetriol stabilized on lactose – PPST-L maintained at room temperature in a polyethylene bag is stable for 3 years. Phosphopropylsilanetriol stabilized on lactose – PPST-L is manufactured in accordance with European Good Manufacturing Practice requirements complying with the requirements of Commission Directive 2003/94/EC.

Phosphopropylsilanetriol stabilized on lactose – PPST-L is proposed as novel food and it can also be incorporated in a range of food categories. To that purpose, Phosphopropylsilanetriol stabilized on lactose – PPST-L has been developed as a highly water-soluble silicon concentration that can be easily used in different food matrices. Phosphopropylsilanetriol stabilized on lactose – PPST-L will be targeted towards general population that want to support their bone and joint health.

The anticipated dietary intake for Phosphopropylsilanetriol stabilized on lactose – PPST-L has been estimates to 3-12 mg silicon/day corresponding to 0.05-0.2 mg/kg body weight/day in a 60 kg person. The maximum use level of Phosphopropylsilanetriol stabilized on lactose – PPST-L, of 600 mg/serving, corresponding to a maximum dose of 12 mg silicon per day as recommended by the manufacturer can be assumed without prejudice to the specific provisions of Directive 2002/46/EC.

Phosphopropylsilanetriol stabilized on lactose – PPST-L is not nutritionally equivalent to other foods and it is not intended to replace other foods currently on the market. Phosphopropylsilanetriol stabilized on lactose – PPST-L is not anticipated to adversely impact the quality of the diet; and comprises almost 100 % of carbohydrates 78 g/100 g, with no fat (0%) and no protein (0%).

Absorption and bioavailability of Silicon (Si) from Phosphopropylsilanetriol stabilized on lactose – PPST-L were determined using both *in vitro* and *in vivo* approaches. Human intestinal *in vitro* models based on differentiated Caco-2 cells was used in compliance with the EFSA guidance on safety evaluation of sources

of nutrients and bioavailability of nutrient from the sources (Food (ANS) et al. 2018). The absorption of Si was also investigated *in vivo*. The average bioavailability of oral Si-deriving from Phosphopropylsilanetriol stabilized on lactose – PPST-L is 10.4%.

The safety of Phosphopropylsilanetriol stabilized on lactose – PPST-L is supported by product specific and non-product-specific studies on silicon, and no genotoxic effects were observed. Collectively, the scientific evidences presented herein demonstrate that Phosphopropylsilanetriol stabilized on lactose – PPST-L would not produce adverse health effects on human health under the intended conditions of use. This novel food will be commercialized on the European market under both trade names Phosphopropylsilanetriol stabilized on lactose – PPST-L.