SUMMARY OF THE DOSSIER

a) Name and address of the applicant

H.C. CLOVER PRODUCTOS Y SERVICIOS, S.L.
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28500 ARGANDA DEL REY
MADRID

b) Name and description of the novel food

Lactitol for use in food supplements as defined in Directive 2002/46/EC (marketed in ampoules of liquids, drop dispensing bottles, and other similar forms of liquids) intended for the adult population.

The lactitol used complies with the description included in COMMISSION IMPLEMENTING DECISION (EU) 2017/450 of 13 March 2017: *"Crystalline powder or colourless solution manufactured via catalytic hydrogenation of lactose. Crystalline products occur in anhydrous, monohydrate and dihydrate forms. Nickel is used as a catalyst."*

Identity of lactitol

Chemical name	4-O-β-D-Galactopyranosyl-D-glucitol
Chemical formula	$C_{12}H_{24}O_{11}$
Molecular weight	344,31 g/mol
CAS No	585-86-4

Description: Crystalline powder or colourless solution manufactured via catalytic hydrogenation of lactose. Crystalline products occur in anhydrous, monohydrate and dihydrate forms. Nickel is used as a catalyst.

Parameters	Specification value
Solubility (in water)	Very soluble in water
Specific rotation	[α] D^{20} = + 13° to + 16°
Assay	Not less than 95 % d.b (1)
Water content	Not more than 10,5 %
Other polyols	Not more than 2,5 % d.b
Reducing sugars	Not more than 0,2 % d.b
Chlorides	Not more than 100 mg/kg d.b
Sulphates	Not more than 200 mg/kg d.b
Sulphated ash	Not more than 0,1 % d.b
Nickel	Not more than 2 mg/kg d.b
Arsenic	Not more than 3 mg/kg d.b
Lead	Not more than 1 mg/kg d.b

(1) d.b — expressed on the dry weight basis

(e) Scientific evidence demonstrating that the novel food does not pose a safety risk to human health

Commission Implementing Decision (EU) 2017/450 authorized, in accordance with Regulation (EC) No 258/97 of the European Parliament and of the Council, the placing on the market of lactitol as a novel food for use in food supplements in the form of capsules or tablets, intended for the adult population.

This decision was subsequently amended by COMMISSION IMPLEMENTING REGULATION (EU) 2018/1293 of 26 September 2018, extending the use of lactitol in powdered food supplements.

This application refers to the modification of the conditions of use of the new food lactitol consisting of including lactitol as an authorized form for use in liquid food supplements.

In fact, the way to use powdered food supplements is to dissolve them in a liquid before ingesting, instead of already providing the solution ready for consumption that is the subject of this application, providing the consumer with another form of presentation that makes it easier its use.

This modification cannot have an impact on human health since the proposed level of use of the novel food lactitol in the same food category corresponds to the currently authorized maximum content.

Reasons why the use of the novel food complies with the conditions laid down in Article 7 of Regulation (EU) 2015/2283.

The lactitol under this request complies with the following conditions:

(a) the food does not, on the basis of the scientific evidence available, pose a safety risk to human health.

(b) the food's intended use does not mislead the consumer, especially when the food is intended to replace another food and there is a significant change in the nutritional value.

(c) where the food is intended to replace another food, it does not differ from that food in such a way that its normal consumption would be nutritionally disadvantageous for the consumer.

Lactitol is already approved as a Novel Food in UE. The modification of utilization conditions doesn't influence the safety of the substance since the specifications of lactitol will remain the same. Furthermore, the product does not mislead the consumer due to it has clear specific conditions of use and additional specific labelling requirement.