Summary of the application: Lysophosphatidylcholine (LPC)-containing oil extract of Antarctic krill (*Euphausia superba*)

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LPC-rich oil extract of Antarctic krill is a new product consisting of Antarctic krill oil extract from *Euphausia superba* containing minimum 18% by weight lysophosphatidylcholine (LPC). The product is produced via enzymatic hydrolysis of Antarctic krill oil that selectively cleaves the fatty acid at the sn-1 position of phosphatidylcholine resulting in the LPC-form of omega-3 fatty acids and free fatty acids. LPC-rich oil extract of Antarctic krill is to be used as an ingredient only in food supplements in the European Union (EU), in accordance with Directive 2002/46/EC. It will not replace any other food in the diet but will supplement the regular daily diet and may be used as an alternative to other omega-3 long chain fatty acid containing food supplements. Under the recommended daily intake levels, the mean dietary exposures to LPC, eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) would be 360, 219 and 125 mg/day, respectively. The Applicant intends to sell the LPC-rich oil extract of Antarctic krill in bulk through a business-to-business model to food supplement manufacturers and marketers, but not to sell it directly to the consumers.

LPC-rich oil extract of Antarctic krill is produced from 'Lipid extract from the crustacean Antarctic Krill (*Euphausia superba*)' that is manufactured as described in Commission Implementing Regulation (EU) 2017/2470 on Union list of novel foods. First, cooked dried krill (krill meal) is subject to solvent extraction to isolate lipids (krill oil). Krill oil is enzymatically treated with phospholipase to increase the fraction of LPC. The enzyme is inactivated, and extraction solvents and residual water are removed by evaporation.

Safety of the novel food LPC-rich oil extract of Antarctic krill is well characterised chemically and has a body of toxicological and clinical data supporting its safety. There are no chemical and microbiological impurities present in LPC-rich oil from Antarctic krill that will pose potential health risks at the proposed use levels. LPC-rich oil extract of Antarctic krill does not contain small particles in nanosize. Data on toxicokinetics show that all constituents of LPC-rich oil extract of Antarctic krill are normally consumed lipids or lipid metabolic intermediates and absorption, distribution, metabolism, and excretion (ADME) of the constituents of LPC-rich oil extract of Antarctic krill, including eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), follow normal fatty acid energy pathways in animals and humans.

LPCs are part of the normal diet (in seafood) and are also formed in the small intestine when phospholipids are hydrolysed by endogenous enzymes. LPC can then be further converted to glycerylphosphorylcholine and hydrolysed to choline. After oral administration, greater than 90 % of phosphatidylcholine (PC) is absorbed by the intestinal mucosa via conversion to LPC. Dietary EPA-LPC and DHA-LPC are readily absorbed into the plasma after ingestion and cross the blood brain barrier. Several animal studies have indicated that EPA and DHA long chain polyunsaturated fatty acids (LC-PUFA) delivered in the form of LPC is taken up to a greater extent by the brain than other forms of these LC PUFAs.

LPC-rich oil extract of Antarctic krill did not show any mutagenic or genotoxic activity in the battery of Organization for Economic Co-operation and Development (OECD) compliant mutagenicity/genotoxicity assays.

A good laboratory practice (GLP)-compliant 90-day repeated dose oral toxicity study with a recovery period was conducted in accordance with OECD TG 408 and the US Food and Drug Administration (U.S. FDA) Redbook guidelines. Under the conditions of the study and based on the toxicological endpoints evaluated, the no-observed-adverse-effect level (NOAEL) was identified to be 2500 mg/kg bw/day for male and female rats. The intended dietary intake of LPC-rich oil extract of Antarctic krill is at its maximum approximately 21 mg/kg bw/day (1.5 g/day). This intake is below the acceptable daily intake (ADI) of 25 mg/kg bw/day (1.75 g/day) defined by the oral toxicity study, and therefore, is not a safety concern. The margin of safety (MOS) between the identified NOAEL of 2500 mg/kg bw/day and the intended dietary intake of LPC-rich oil extract of Antarctic krill of 21 mg/kg bw/day is 120. This MOS is viewed appropriate to conclude that LPC-rich oil extract of Antarctic krill at its intended use levels in food supplements is safe. None of the safety studies on LPC-rich oil extract of Antarctic krill (including the 90-day study) nor safety studies on the source Antarctic krill oil raise any safety concerns related to reproductive and developmental toxicity. No significant adverse effects have been associated with the consumption of the source Antarctic krill oil in human studies.

Due to their allergenic potential, crustaceans and products thereof need a specific labelling in the EU.

Overall, based on the available body of animal and human safety data conclusively support that LPC-rich oil extract of Antarctic krill is safe under the intended intake level of up to 1.5 g/day.