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General declaration for Dry Microencapsulated Extracts with Sodium Alginate

I, the undersigned Lindita Vrush as Legal Representative of the Company AMEL Extract sh.p.k., with registered office in Elbasan/Albania, VAT number M52909202G, Email: linditavrushi@esencial.al Phone : +355 69 243 0707, Web: www.esencial.al

Declare that:

Dry Microencapsulated Extracts with Sodium Alginate comply with the following Declarations:

1. Regulation (EU) 2015/2283, with the amendments of 03.27.2021, which repeals Regulation (EC) no. 258/97 and the Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 for the establishment of the Union list of novel foods in accordance with Regulation (EU) 2015/2283, is not considered "New" as it was used for human consumption on a significant scale in the Union before 15 May 1997.
2. Reg. No. CAS 124-38-9) is generally recognized as safe (GRAS) as a direct food ingredient for humans based on current conditions of use of good manufacturing practices: the ingredient is used as an agent desiccant as defined in § 170.3(o)(17) of this chapter; a processing allowance as defined in § 170.3(o)(24) of this chapter; and a propellant, a venting agent, and a gas as defined in § 170.3(o)(25) of this chapter.
3. Regulation (EU) no. 231/2012 of the Commission "additives other than colors and sweeteners" in which sodium alginate (E401) is considered an authorized food additive and classified as safe approved by the US Food and Drug Administration (FDA) and by the European Union Authorities for Food Safety (EFSA), as well as the Joint FAO/WHO Expert Committee on Food Additives (JECFA).
4. Regulation (EC) no. 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on food products. EFSA, Regulation (EC) n. 1924/2006, 2006.
5. FDA, Guidance on Food Labeling and Education Act (NLEA) Requirements, 1994.



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6. Statement on Heavy Metals according to Commission Regulation (EU) 2023/915 of April 25, 2023 on maximum levels for certain pollutants in food and amendments of 10/08/2023, / for Pb in categories 3.1 and for Cb in categories 3.2.
7. Commission Regulation (EU) 2023/915 of April 25, 2023 on maximum levels for certain contaminants in food and the repeal of Regulation (EC) No. 1881/2006 and amendments dated 10/08/2023 Annex 1, Category 5 on the processing of pollutants and subcategory 5.1 on polycyclic aromatic hydrocarbons (PAHs)
8. Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients (Recast) Annex II, Part II and III+ Directive 59/2010/EC
9. Regulation (EC) No. 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum levels of pesticide residues in or in food and feed of plant and animal origin and amending Council Directive 91/414/EEC with amendments of 26 /02/2024
10. Commission Regulation (EU) 2023/915 of April 25, 2023 on maximum levels for certain contaminants in food and the repeal of Regulation (EC) No. 1881/2006 and amendments dated 10/08/2023 Annex 1, Category 1 on mycotoxins and subcategory 1.1 about aflatoxins
11. Regulation (EC) no. 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of food products about bacterial count.
12. Regulation of the Commission (EC) no. 2073/2005 of 15 November 2005 on microbiological criteria for foods, Annex 1 on microbiological criteria for foods, chapter 1 on food safety criteria and chapter 2 on process hygiene criteria, and Commission Regulation (EU) 2023/915 of 25 April 2023 on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006 amended on 10/08/2023 about yeast and mould.
13. Regulation of the Commission (EC) no. 2073/2005 of November 15, 2005 on microbiological criteria for foods, Annex 1 on microbiological criteria for foods, chapter 1 on food safety criteria and chapter 2 on process hygiene criteria on salmonella and escherichia coli.



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14. GMOs are not produced "by" or "from" as these terms are used in Council Regulation (EC) No. 834/2007 of June 28, 2007 on organic production and labeling of organic products and the repeal of Regulation (EEC) No. 2092/91 with the changes made on 01/01/2022, article 2 and 9 and Regulation (EC) No. 1829/2003 of the European Parliament and of the Council of September 22, 2003 on food and feed for genetically modified animals with the changes made on 27/03/2021 c) Regulation (EC) No. 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labeling of genetically modified organisms and the traceability of foodstuffs and foodstuffs produced from genetically modified organisms and amending Directive 2001/18/EC as amended made on 26/07/2019
15. Regulation no. 828/2014, dated July 30, 2014, "On the requirements for providing information to consumers about the absence or reduced presence of gluten in food according to the Annex to the Declarations about the absence or reduced presence of gluten in foods that are allowed to be made and their conditions
16. Regulation (EU) No. 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of nutritional information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing the Directive of Commission 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5 /EC and Commission Regulation (EC) No. 608/2004, Annex II
17. Commission Decision (EU) 2018/1701 of 7 November 2018 on the proposed citizens' initiative entitled "Mandatory labeling of non-vegetarian/vegetarian/vegan food" (notified under document C(2018) 7300) and Regulation (EC) No. 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies, Article 2 and 3
18. Commission Regulation (EU) 2023/915 of 25 April 2023 on maximum levels for certain contaminants in food, Annex I, category 6, subcategory 6.2 about melamine
19. Directive 1999/3/EC of the European Parliament and of the Council of February 22, 1999 on the establishment of a Community list of foods and food ingredients treated with
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radiation and Directive 1999/2/EC of the European Parliament and of the Council of 22 February 1999 on the approximation of the laws of the Member States regarding foods and food ingredients treated with ionizing radiation as amended on 11/12/2008

20. Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of November 30, 2009 for cosmetic products (reformed) amended on 04/04/2024, Chapter II, Article 18; Chapter V, Article 11 about animal testing.
21. Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of November 30, 2009 for cosmetic products (reformed) amended on 04/04/2024, Article 16 about Nanomaterials.
22. Commission Regulation (EU) 2022/1396 of August 11, 2022 amending the annex to Regulation (EU) No. 231/2012 that defines the specifications for food additives listed in annexes II and III of Regulation (EC) no. 1333/2008 of the European Parliament and of the Council regarding the presence of ethylene oxide in food additives and Commission Regulation (EU) No. 231/2012 dated March 9, 2012 that defines the specifications for food additives listed in annexes II and III of Regulation (EC) No. 1333/2008 of the European Parliament and the Council
23. Declaration of Substances (Natural Extracts) Generally Recognized as Safe (GRAS) under the FDA Code of Regulations, Title 21, Chapter 1, Subchapter B, Part 182/Subpart A/182.20
24. FDA Code of Regulations, Title 21, Chapter 1, Subchapter B, Part 172/Subpart F
25. Packaging standard ISO 15378:2011 in accordance with Regulation (EC) no. 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and objects intended to come into contact with food and which repeals Directives 80/590/EEC and 89/109/EEC
26. Carbon dioxide (e.g. CO₂, CAS Reg. No. 124-38-9) is generally recognized as safe (GRAS) as a direct ingredient of human food. CO₂ gas is used: 1 drying agent as defined in § 170.3(o)(17) /2 processing aid as defined in § 170.3(o)(24) of this chapter /3 a propellant, a blowing agent, and a gas as defined in § 170.3(o)(25)

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27. The technological application equipment for the extraction of supercritical fluids (SCFE CO₂) are produced according to the following directives: a) Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014 for the harmonization of the laws of the States members with regard to the making available on the market of pressure equipment. b) Directive 97/23/EC of the European Parliament and of the Council of 29 May 1997 on the approximation of the laws of the Member States relating to pressure equipment
28. Statement on recommended phytocomponent testing according to the European Pharmacopoeia and ISO 1124- and ISO 1124-2 standards) for the evaluation of chemical compounds, secondary metabolites and active ingredients using standardized test methods GC-FID, HPLC, ELISSA, quality guaranteed raw material.