

1. PRODUCT DESCRIPTION

Code:	F0780
Name:	MOBILEE ROOSTER COMB EXTRACT
Chemical Name and description:	Oral Hyaluronic Acid from rooster combs extract
Product intended use:	Food supplement ingredient.
Regulatory status:	New Dietary Ingredient (USA) exempt from notification, Food Supplement Ingredient (EU)
Composition:	MOBILEE for food consumption is a natural 100% rooster comb extract that contains between 60-75% of sodium hyaluronate, 5-15% of sulfated polysaccharides and 5-20% of hydrolyzed collagen prevailing of TYPE I.
Raw material origin:	Animal origin, chicken. Rooster combs from which MOBILEE is obtained are also declared as food grade and fit for human consumption. Rooster combs are obtained from <u>European slaughterhouses</u> authorized by the competent authorities.
Storage and packaging:	Not special storage conditions are required. Packaged in a triple-chamber bag in a metal drum. Ingredient in BULK.
Shelf life /Expiration period:	3 years from the manufacture date.

2. PRODUCT SPECIFICATION

Class	Parameter	Reference Method	Limits
DESCRIPTION	Appearance	Visual inspection	Off-white hygroscopic powder
PHYSICO-CHEMICAL and CHEMICAL TESTS	pH	EP 2.2.3	5.0 - 8.5
	Loss on drying	EP 2.2.32	Not more than 10%
	Nitrogen	EP 2.5.9	Not more than 8%
	Chlorides	EP 2.4.4	Not more than 1%
	Sodium hyaluronate content (on dried basis)	EP 1472, ASSAY	60 - 75%
	Sulfated Polysaccharides	EP 0333, Related substances	5-15 %
	Collagen	EP 2.2.56, Hydrolysis method 1, Derivatization method 7	5-20 %
	Lead	EP 2.2.58	Not more than 3.0 ppm
	Mercury	EP 2.2.58	Not more than 0.10 ppm
	Cadmium	EP 2.2.58	Not more than 1.0 ppm
	Arsenic	EP 2.2.58	Not more than 1 ppm
	Chromium	EP 2.2.58	Not more than 10 ppm
MICROBIOLOGICAL TEST	Total viable aerobic count	EP 2.6.12	Not more than 10 ³ cfu/g
	E. Coli	EP 2.6.13	Absence/g
	Salmonella	EP 2.6.13	Absence/25g
	S. Aureus	EP 2.6.13	Absence/g
	P. Aeruginosa	EP 2.6.13	Absence/g

3. NUTRITIONAL INFORMATION

TESTS	% W/W
Energy	997 kJ (100g) / 240 kcal (100g)
Dietary Fiber	46.20
Total ash (550°C)	9.73
Carbohydrates	0.03
Moisture	7.19
Fats	< 0.25
Protein	36.85
Salt	8.75
Sodium (as Na)	3.50

4. ALLERGENS INFORMATION

Bioiberica considers allergens as defined by the European Regulation 1169/2011 ("EU") and amendments Directives 2000/13/EC and 2007/68/EC and the US Food Allergen Labeling Consumer Protection Act of 2004 ("FALCPA").
We Bioiberica **do not use them** in **MOBILEE** process.

ALLERGEN	PRESENT	CROSS-CONTACT	ALLERGEN	PRESENT	CROSS-CONTACT
Cereals containing gluten and products thereof	NO	NO	Nuts and products thereof	NO	NO
Crustaceans, and products thereof	NO	NO	Celery (and celeriac) and products thereof	NO	NO
Eggs and products thereof	NO	NO	Mustard and products thereof	NO	NO
Fish and products thereof	NO	NO	Sesame seed and products thereof	NO	NO
Peanuts and products thereof	NO	NO	Sulphur dioxide, preservative found in some dried fruit and sulphites >10 mg/kg	NO	NO
Soybeans and products thereof	NO	NO	Lupin and products thereof	NO	NO
Milk and products thereof (incl. lactose)	NO	NO	Molluscs, e.g. clams, mussels and products thereof	NO	NO

5. OTHER SUBSTANCES

LATEX INFORMATION

Bioiberica **do not use** latex or products containing latex in production process of **MOBILEE**

ADDITIVES INFORMATION

The product **MOBILEE** is not a food additive and neither any additives are added on the final product.

ANTIBIOTIC/HORMONE

MOBILEE has been manufactured in an antibiotic and hormone free environment.

And it does not contain any chemicals or contaminants that are listed by California Proposition 65, also known as The Safe Drinking Water and Toxic Enforcement Act of 1986

WADA LIST

MOBILEE does not contain any substance listed in WADA list to prohibited substance (World-Anti-Doping-Agency)

6. GENETICALLY MODIFIED ORGANISM (GMO)

MOBILEE is not produced using gene technology nor raw materials which are produced using GMO in accordance with the European Union (EU) regulations 1829/2003 and 1830/2003. Therefore, in reference to EU regulations, it is not necessary to label the product as a GMO product.

7. BSE/TSE INFORMATION

MOBILEE manufactured in Bioiberica is obtained from rooster combs. The slaughterhouses supplying all raw materials have the relevant CEE authorization implying, along with other things, that the animals slaughtered are subject to veterinary examination.

According to the guideline “**EMA/410/01: Note for guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products**”, rooster combs are not naturally susceptible to TSE infection via the oral route and they are not TSE-relevant animal species within the meaning of this note for guidance. Therefore, there are NO risks of transmission of BSE by Bioiberica’s **MOBILEE** bearing in mind that the rooster combs used are not from ruminant origin.

8. APPLICABLE LEGISLATION

The product **MOBILEE** fulfills the contents regulated for (and its amendments):

Commission Regulation (EC) No 2023/915 on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006

Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs

Council Directive 86/363/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on foodstuffs of animal origin

Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive Text with EEA relevance

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

5.4 of the Ph. Eur. and Note for Guidance on Impurities: Residual Solvents (ICH Q3C)

SOLVENTS

The solvents likely to be present are acetone and ethanol (Class 3) Not more than 5000 ppm

9. IRRADIATION

We hereby declare that the product **MOBILEE** is not irradiated with gamma irradiation at any point of the production process.

10. PACKAGING

We hereby certify that the plastic bags used as primary packaging material of our products are periodically analyzed in accordance to the Ph. Eur. monograph 3.1.3 *Polyolefins*, and that the manufacturer of the plastic bags complies with the following applicable European regulations:

European Commission Regulation No 10/2011, as amended, on plastic materials and articles intended to come into contact with food.

European Commission Regulation No 1935/2004, as amended, on materials and articles intended to come into contact with food.

European Commission Regulation No 2023/2006, as amended, on good manufacturing practice for materials and articles intended to come into contact with food.

U.S regulations concerning substances for uses as basic components of single and repeated use food contact surfaces (21CFR 177.1520 Olefin polymers)

11. PRODUCED BY

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