

CE BATCH COMPLIANCE STATEMENT

Product name	Happy Caps Brain e
Version	5
Issue Date	31-01-2023
Batch number	C1122-5


BLEND INGREDIENTS (PER CAPSULE)

Rhodolia Rosea extract	100mg
L-Tryptophan	100mg
Choline	100mg
DMEA	75mg
Gaba	75mg
L-Theanine	60mg
L-Carnitine	50mg
Caffeine	25mg
Niacine	15mg

REGULATORY

Specification	The information in this specification is based on careful examinations and is given to the best of our knowledge This product is a Happy-Caps Sport & Food supplement. REG. (EU) 1924/2006
Batch number and traceability	By means of the quality management system each blend has an unique batch number. Every batch number is documented during the production process and the end-product receives a new batch number which is also documented and is part of the labels. Because of that the traceability is ensured at any time both during production and delivery. Moreover the traceability can be confirmed at any time by the initial supplier according to regulation (EC) No 178/2002.
Shelf life	Check the BBE date on the packaging

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Terms of transport and storage	<p>Storage conditions (In the warehouse): finished product warehouse: 2-25<, humidity <65%</p> <p>Storage conditions (During the transport-Short term): Seal airtight and keep in dry place apart from damp, light, poisonous and noxious matters.</p>
Country of Origin	<p>Country of origin: Netherlands Happy Caps Arnhemseweg 55A, NL-7331BB info@happy-caps.com - www.happy-caps.com</p> 
Packaging	<p>We confirm that the packing materials used is in compliance with:</p> <ul style="list-style-type: none"> - Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs. - Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC - Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food.
Packing	<p>Mixing and packing meets the requirements of IFS Food version 6.1 and other associated normative documents.</p>
Ionizing / Radiation	<p>We confirm the product is not made from irradiated/ionized raw materials or was irradiated/ionized in accordance with directives 1992/2/EC and 1999/3/EC.</p>
GMO statement	<p>We herewith confirm, that our product is not genetically modified food and/or does not contain food, additives or flavours produced from genetically modified organisms in accordance to regulations (EC) No 1829/2003 and 1830/2003.</p>
Botanical ingredients	<p>All capsules are made in the European Union and made of raw materials and coloring CE and FDA approved. Since the blend contains botanical ingredients, there is likely to be minor colour variations between different batches because of geographical and seasonal variations of the raw material. A thorough inspection ensures that these variations do not impact the overall quality of the finished product.</p>
Foreign Bodies Detection	<p>Metal detector: Yes Sieve Blending: Yes Sieve Packaging: Yes X-Ray: No Other: No</p>

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Frequency of analysis	Frequency of analysis of each contaminant: Every batch Frequency of analysis of each heavy metals: Every batch Frequency of analysis of microbiology: Every batch
Pesticides	To our actual knowledge about the production process, raw materials and equipment used to manufacture the product, potential pesticide residues in this product comply with the European legislation on pesticide residues, specifically regulation (EC) No. 396/2005. However, we additionally test for pesticide residues on a routine basis with an accredited third party laboratory.
Residual solvents	The product meets: - EU DIRECTIVE 2009/32/EC 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 - EU DIRECTIVE 2010/59/EU of 26 August 2010 amending EEG Directive 2009/32/EC
Contaminants	The product is in accordance and meets with the commission regulation (EC) No. 629/2008 of 2 July 2008, amending regulation (EC) No. 1881/2006 setting maximum levels for certain contaminants in foodstuffs.
PCBS and Melamine	The product is in accordance and meets with the commission regulation (EU) No. 594/2012 of 5 July 2012 amending regulation (EC) No. 1881/2006 with regards to the maximum levels of the contaminants ochratoxin a, non dioxin-like PCBS and melamine in foodstuffs.
Allergens	None
Anti-Doping	As per the list of 2020 of the world anti-doping agency none of the ingredients are a doping substance nor a combination of doping substances. The product does not contain any doping substance. The products does not contain any ingredient derived from a doping substance.
Nanomaterials	According to the the definition of 'nanomaterials' of the EU Regulation No. 1169/2011 of 25 October 2011, on the provision of food information to consumers , we hereby attest that no nanomaterials are used in the formulation nor in the packaging materials of our product.
Hygiene	Happy Caps complies with Regulation (EC) No. 852/2004 of 29 April 2004 on the hygiene of foodstuffs.

ANALYTICAL DATA

Characteristics	Test Method	Units	Specifications	Results
Hypromellose identification	VCPP010		Positive	pass
Identification of iron oxides	VCPP011		Conforms to composition	pass
Identification of titanium dioxide	VCPP017		Conforms to composition	pass
Disintegration time	VCPP001	min/sec	Less than 15:00	04:13
Loss on drying	VCPP012	%	Less than 9.0	4.3
Sulphated ash	VCPP013	%	Less than 6	pass
Total Aerobic Microbial Count	VCPP031	cfu/g	Less than 1000	40
Escherichia coli	VCPP032		Absence in 1 gram	pass
Salmonella	VCPP033		Absence in 10 gram	pass
Staphylococcus aureus	VCPP034		Absence in 1 gram	pass
Total Yeasts/	VCPP035		Less than 100	<10
Moulds Count Pseudomonas aeruginosa	VCPP036	cfu/g	Absence in 1 gram	pass

ELEMENTAL IMPURITIES / HEAVY METALS

With reference to ICH Q3D and other applicable standards controlling levels of elemental impurities in drug products and food supplements, the capsule products are meeting below levels of applicable elements. Monitoring testing is in place under validated methods.

Element	Unit	Acceptance Level
Arsenic	ppm	Not more than 1.5
Lead	ppm	Not more than 1.0
Cadmium	ppm	Not more than 0.5
Mercury	ppm	Not more than 0.1
Cobalt	ppm	Not more than 5
Vanadium	ppm	Not more than 10
Nickel	ppm	Not more than 20