

CE BATCH COMPLIANCE STATEMENT

Product name	Happy Caps Brain-E
Version	V1.1 Notification Nr.: 2023/12/21/SD/AF6ADB
Issue Date	January 2024
Batch number	TBA
GTIN Number	8720938600074 Global Trade Item Number
Registration According EU	Vitae Care Sp. Z o.o. https://e.sanepid.gov.pl/spoz/rpop 175363

BLEND INGREDIENTS (PER CAPSULE)

Rhodiola Rosea L.	100mg
Choline	100mg
L-Tryptophan	100mg
GABA (Gamma Aminobutyric Acid)	75mg
L-Theanine	60mg
L-Carnitine	50mg
L-Arginine	50mg
Caffeine	25mg
Niacine	5mg

REGULATORY

Specification	<p>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</p> <p>Pursuant to Article 29, clause 1 of the Act of 25 August 2006 on food and nutrition safety (OJ of 2019, item 1252) Notifies of placing for the first time on the market of the Republic of Poland, dietary supplement Happy-Caps EUPHORY-E</p> <p>Approved by Chief Sanitary Inspector, Jo. Targowa 65, 03-729, Warsaw, Poland, granted to distribute by VITAE CARE SPOLKA, ul. Biala 4 Ste 20A, 00-895, Warsaw, Poland</p>
Batch number and traceability	<p>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.</p>
Shelf life	<p>Check the BBE date on the packaging</p>

HAPPY CAPS®

Terms of transport and storage	Storage conditions (In the warehouse): finished product warehouse: 2-25<, humidity <65% Storage conditions (During the transport-Short term): Seal airtight and keep in dry place apart from damp, light, poisonous and noxious matters.
Country of Origin	Country of origin: Netherlands Happy Caps - Arnhemseweg 55A, 7331BB, Apeldoorn, Netherlands. info@happy-caps.com - www.happy-caps.com
Packaging	We confirm that the packing materials used is in compliance with: - 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	Mixing and packing meets the requirements of IFS Food version 6.1 and other associated normative documents.
Ionizing / Radiation	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.
GMO statement	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.
Botanical ingredients	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.
Foreign Bodies Detection	Metal detect: Yes Sieve Blend: Yes Sieve Package: Yes X-Ray: No Other: No
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 Total	VCPP034		Absence in 1 gram	pass
Yeasts/Moulds Count Pseudomonas aeruginosa	VCPP035 VCPP036	cfu/g	Less than 100 Absence in 1 gram	<10 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

EUROPEAN COMMUNITY PRODUCT REGISTRATION

Official Certified Translation Polish > English for European Community Registration in Poland

CERTIFIED TRANSLATION FROM POLISH

[the translator's comments are made in square brackets]

Registration / Notification number: 2023/12/21/SD/AF6ADB

[no entry]
date

Chief Sanitary Inspector
ul. Targowa 65
03-729 Warsaw

NOTIFICATION of placing for the first time on the market of the Republic of Poland

VITAE CARE SPÓŁKA Z OGRANICZONĄ ODPOWIEDZIALNOŚCIĄ, ul. Biała 4 suite 20A,
00-895 Warsaw, Poland, TIN: 5272906869

(name and surname or business name and address of the entity that submits the notification of placing or the intention to place for the first time on the market and TIN, if the entity holds this number)

pursuant to Article 29 clause 1 of the Act of 25 August 2006 on food and nutrition safety (OJ of 2019, item 1252) notifies of placing for the first time on the market of the Republic of Poland:

dietary supplement
(qualification/type of food adopted by the food business operator)

HAPPY CAPS. BRAIN-E
(product name)

capsules
(product form)

HAPPY CAPS®

EUROPEAN COMMUNITY PRODUCT REGISTRATION

Name of ingredient	Quantity per unit	Quantity in daily allowance	Unit	Additional information
Niacin	5	5	mg	
<i>Rhodiola rosea</i> L. (golden root)	100	100	mg	
Arginine	50	50	mg	
Choline	100	100	mg	
GABA (gamma-aminobutyric acid)	75	75	mg	
Caffeine	25	25	mg	
Carnitine	50	50	mg	
Theanine	60	60	mg	
Tryptophan	100	100	mg	

MOJO Nutrition BV Arnhemseweg 55 A 7331 BB Apeldoorn, the Netherlands
(name and surname or business name and address of the manufacturer)

The competent authority of a Member State of the European Union that has been notified of the placing on the market of the food or has authorised placing the food on the market in that country:
None

EUROPEAN COMMUNITY PRODUCT REGISTRATION

EUROPEAN COMMUNITY PRODUCT REGISTRATION

(legible signature of the person authorised to represent the entity notifying of the first placing on the market in territory of the Republic of Poland)

CERTIFIED SIGNATURE

MARTA ŁANOCH

21/12/2023 at 03:11:03 PM (GMT+1)

The document is signed electronically with a certified signature

Appendices:

1. Labelling template in Polish
2. Power of attorney
3. Proof of payment of the stamp duty

Repertory No. 19/2024

I, the undersigned Katarzyna Owczarek, certified translator of English, registered by the Polish Minister of Justice under No. TP/50/12, certify that this is a true and complete translation of the electronic document shown to me.

Warsaw, 3 January 2024

The translator's entry in the above-mentioned register may be verified at: <https://arch-bip.ms.gov.pl/pl/rejestry-i-ewidencje/tlumacze-przysiegli/lista-tlumaczy-przysieglych/translator.10624.html>

Signature

Dokument podpisany przez
Katarzyna Owczarek
Data: 2024.01.03 15:35:56 CET