TECHNICAL DATA SHEET & PRODUCT DOSSIER

BRAIN BOOSTER CAPSULES

1. DOCUMENT CONTROL

Document title	BrainBooster_Technical Data Sheet
Product name	Brain Booster Capsules
Document number	FSC-TDS-003
Version	00
Prepared by	Rimante Jaseviciute
Signature	
Approved by	Sam Mallach
Signature	
Date of signing	2026 06 16

2. COMPANY DETAILS

Brand	Zelená Země s.r.o.
Address	Wuchterlova 523/5, 160 00 Praha 6
Contact	Lucie Garabášová
Email	info@zelenazeme.cz

3. PRODUCT IDENTIFICATION

Product Name	Brain Booster Capsules
Product type	Food supplement (Directive 2002/46/EC)
Regulatory type	Nutritional product
Pharmacological action	The product is not intended to diagnose, treat, cure, or prevent any disease.
Dosage Form	Capsules

Intended Use	Food supplement intended for oral use to support cognitive function, mental clarity, concentration, and brain health.
Target Population	Adults
Route of administration	Oral
Recommended daily intake	1 capsule

4. FORMULA COMPOSITION

Tulsi Leaf Extract, vegetable capsule (hydroxypropyl methylcellulose), Gotu Kola Extract, Ginseng Extract, Bacopa Monnieri-Brahmi Extract, Ginkgo Biloba Extract, Ashwagandha Root Extract, Rhodiola Rosea Extract, anti-caking agent: silicon dioxide.

Ingredient	Amount in one capsule	% NRV*
Tulsi Leaf Extract	210 mg	-**
Gotu Kola Extract	100 mg	-**
Ginseng Extract	70 mg	-**
Bacopa Monnieri-Brahmi Extract	70 mg	-**
Ginkgo Biloba Extract	60 mg	-**
Ashwagandha Root Extract	40 mg	-**
Rhodiola Rosea Extract	20 mg	-**

* % NRV - Nutrient Reference Value (EU).

** NRV not established.

5. ACTIVE INGREDIENT SPECIFICATIONS

Ingredient Name	Tulsi leaf extract (Holy Basil)
CAS number	91845-35-1
EC number	295-208-3
Origin	Botanical — leaves of Ocimum tenuiflorum L. (synonym Ocimum sanctum, Lamiaceae)
Technical data	Standardised to contain not less than 2% ursolic acid
Ingredient Name	Gotu Kola extract 4:1 (Centella asiatica)
CAS number	84696-21-9
EC number	283-640-5
Origin	Botanical — whole herb or aerial parts of Centella asiatica (L.) Urban (Apiaceae)
Technical data	Light brown to beige powder
Ingredient Name	Ginseng extract (20% ginsenosides) (Panax ginseng)
CAS number	84650-12-4
EC number	283-493-7
Origin	Botanical — root of Panax ginseng C.A. Meyer (Araliaceae); hydroalcoholic extraction
Technical data	Light yellowish-brown powder; characteristic odour; min 20% total ginsenosides
Ingredient Name	Bacopa Monnieri extract 10:1 (Brahmi)
CAS number	93164-89-7
EC number	Not assigned

Origin	Botanical — whole aerial parts of Bacopa monnieri (L.) Pennell (Plantaginaceae)
Technical data	Light brown to beige powder; characteristic odour
Ingredient Name	Ginkgo Biloba extract 50:1 (Ginkgo biloba)
CAS number	90045-36-6
EC number	289-896-4
Origin	Botanical — dried leaves of Ginkgo biloba L. (Ginkgoaceae)
Technical data	Light brown to beige powder
Ingredient Name	Ashwagandha root extract 10% withanolides (Withania somnifera)
CAS number	90147-43-6
EC number	290-434-9
Origin	Botanical — root of Withania somnifera (L.) Dunal (Solanaceae)
Technical data	Brownish-yellow powder
Ingredient Name	Rhodiola Rosea extract (Rhodiola rosea)
CAS number	84954-92-7
EC number	Not assigned
Origin	Botanical — root and rhizome of Rhodiola rosea L. (Crassulaceae)
Technical data	Light pink to beige powder

6. EXCIPIENTS & CAPSULE SHELL

Vegetable capsule (hydroxypropyl methylcellulose), anti-caking agent: silicon dioxide.

7. PHYSICOCHEMICAL CHARACTERISTICS

Appearance	Size “00” capsules
Colour	Transparent
Odour	No specific odour
Weight	Capsule weight: 705 mg including capsule (possible deviation ± 10%)
Packaging	75 ml brown glass jar with a 38 mm glossy black lid
Quantity in jar	30 capsules

8. MICROBIOLOGICAL SPECIFICATION

Parameter	Limit	Result
TAMC	< 50 000 CFU/g	Conforms
TYMC	< 500 CFU/g	Conforms
Coliforms	Negative/25 g	Conforms
Salmonella sp.	Negative/25 g	Conforms
E. coli	Negative/1 g	Conforms

9. CONTAMINANT LIMITS

Parameter	Limit (mg/kg)	Reference (EU regulation)
Heavy metals		2023/915
- Lead	3	
- Mercury	0.1	
- Cadmium	1	
Pesticides	0.01 (depending on the pesticide residue)	396/2205
PAHs	10	2023/915
Pyrrolizidine alkaloids	400 microg/kg	2023/915

10.DIRECTIONS FOR USE

Take 1 capsule daily with a sufficient amount of water, preferably with a meal, or as directed by a healthcare professional. Do not exceed the recommended daily dose.

11. MANDATORY WARNINGS

Do not exceed recommended daily dose. Food supplements should not be used as a substitute for a varied diet. It is important to adhere to a balanced and varied diet and a healthy lifestyle. Keep out of reach of children.

12. STORAGE CONDITIONS

Store in a dry place at temperatures up to 25°C. Protect from direct sunlight. Keep out of reach of children. The manufacturer is not liable for damages caused by improper use or storage.

13. SHELF LIFE

Shelf life: 24 months when stored under recommended conditions and in the original sealed packaging. The best-before date is indicated on the packaging.

14. PACKAGING INFORMATION

Packaging type	75 ml brown glass jar with a 38 mm glossy black lid; label dimensions 130 × 50 mm
Material	
Pack size	
Net quantity	
Primary packaging supplier	

15. MANUFACTURING DATA

Manufacturer	AST Commerce & Co. s.r.o.
Certifications	Available upon request
GMP status	No

HACCP	Yes
ISO certificate	ISO 22716

16. REGULATORY STATUS

Physical and chemical requirements	The product complies with the requirements of Commission Regulation (EC) No. 1881/2006 (as referenced in original Czech TDS), which sets maximum levels for certain contaminants in foodstuffs.
Allergens	We declare that the product does not contain any allergens as defined by Regulation (EU) No. 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers. The possibility of cross-contamination of the product during manufacturing and storage has been completely excluded based on hazard analysis.
GMO	In accordance with Regulations (EC) No. 1829/2003 and 1830/2003, the product does not contain GMOs and has not been produced from genetically modified raw materials.
Ionization	The product has not been treated with ionizing radiation as defined in Directive 1999/2/EC of the European Parliament and of the Council, as amended by Regulation (EC) No. 1137/2008.

17. TRACEABILITY

Batch coding format	First three letters represent product code. Next two digits are the sequential number of products made that year. Next to it expiry date appears.
Traceability status	Fully traceable
Recall procedure reference	Available upon request

18.QUALITY CONTROL RELEASE

Test	Specification	Method
Identity (appearance)	Conforms to description	Visual
Assay	90-110 % of label claim	HPLC or GC
Uniformity	Complies with Ph. Eur. 2.9.40	Mass variation or content uniformity
Microbiological quality (Ph. Eur. 5.1.4)	As described in Section 6	Microbial enumeration tests and tests for specified microorganisms
Heavy metals, pesticides, mycotoxins	As described in Section 7	ICP, HPLC, GC
Residual solvents	As per Ph. Eur. 2.4.24	HPLC, GC

19. SAFETY ASSESSMENT SUMMARY

Compound	Acute toxicity	Repeated-dose toxicity	Genotoxicity	Reproductive toxicity	Metabolism	Safety classification
Tulsi leaf extract / Ocimum tenuiflorum (Holy Basil)	Acute oral LD50 >2000 mg/kg bw (rat, OECD TG 423)	Subchronic NOAEL >2000 mg/kg bw/day (rat, 90-day oral); no adverse effects observed	Not genotoxic; Ames test negative; eugenol and rosmarinic acid tested negative in standard genotoxicity assays	Not classified; no reproductive or developmental effects at dietary doses; NOAEL >2000 mg/kg bw/day (rat)	Eugenol, rosmarinic acid, and ursolic acid absorbed in GI tract; hepatic glucuronidation and sulphation; renal excretion	Safe at supplemental doses; EMA HMPC traditional use established; not recommended during pregnancy at high doses; may potentiate anticoagulant therapy
Gotu Kola extract 4:1 / Centella asiatica	Acute oral LD50 >5000 mg/kg bw (rat); not classified; GRAS status	Subchronic oral NOAEL >300 mg/kg bw/day (rat); no adverse effects at supplemental doses; 90-day human studies at 60–180 mg/day show good tolerability	Not genotoxic; asiaticoside and madecassoside Ames test negative; no clastogenic activity identified	Not recommended during pregnancy (emmenagogue properties in traditional use); not classified as reproductive toxicant at supplemental doses	Triterpene saponins (asiaticoside, madecassoside) absorbed and hydrolysed to aglycones; hepatic metabolism; renal and faecal excretion	Safe at supplemental doses; EMA HMPC monograph established; not recommended during pregnancy; rare hepatotoxicity cases reported with prolonged high-dose use
Ginseng extract (20%	Acute oral LD50 >5000 mg/kg bw (rat, OECD TG	Subchronic oral NOAEL >200 mg/kg bw/day	Not genotoxic; ginsenosides Ames test	Not classified; no reproductive or developmental	Ginsenosides absorbed and deglycosylated by	Safe at supplemental doses (200–400

Compound	Acute toxicity	Repeated-dose toxicity	Genotoxicity	Reproductive toxicity	Metabolism	Safety classification
ginsenosides) / Panax ginseng	401); not acutely toxic	(rat); EMA HMPC monograph; human studies at 200–400 mg/day well-tolerated	negative; no clastogenic activity identified	toxicity at dietary doses; NOAEL >1500 mg/kg bw/day	intestinal microbiota to compound K and other aglycones; hepatic metabolism; renal and faecal excretion; half-life 3–6 hours	mg/day); EMA HMPC monograph established; not recommended during pregnancy; may interact with warfarin, digoxin, and MAOIs; insomnia at high doses
Bacopa Monnieri extract 10:1 (Brahmi)	Acute oral LD50 >2000 mg/kg bw (rat); not classified; human studies at 300–450 mg/day generally well-tolerated; GI side effects (nausea, cramping) at high doses	Subchronic oral NOAEL >500 mg/kg bw/day (rat); human RCTs at 300–450 mg/day show acceptable tolerability; GI tolerability improved by taking with food	Not genotoxic; bacosides Ames test negative; no clastogenic activity; standard genotoxicity battery negative	Not recommended during pregnancy (insufficient safety data); spermatogenic effects observed in animal studies at very high doses — not relevant at supplemental doses; not classified as reproductive toxicant	Bacosides absorbed in GI tract; hepatic hydrolysis to aglycones (ebelin, jujubogenin); wide tissue distribution; hepatic glucuronidation; renal and faecal excretion; onset of cognitive effects typically 8–12 weeks	Safe at supplemental doses (300–450 mg/day); not recommended during pregnancy; take with food for GI tolerability; CYP3A4 inhibition at high doses possible; cognitive effects require consistent use for several weeks
Ginkgo Biloba extract 50:1	Acute oral LD50 >2000 mg/kg bw (rat)	Subchronic oral NOAEL >500 mg/kg bw/day (rat); no adverse	Not genotoxic; bacosides Ames test negative; no clastogenic	Not recommended during pregnancy; ginkgolides inhibit	Terpene lactones (ginkgolides A/B/C, bilobalide) rapidly absorbed;	Safe at supplemental doses (120–240 mg/day

Compound	Acute toxicity	Repeated-dose toxicity	Genotoxicity	Reproductive toxicity	Metabolism	Safety classification
		hepatic or renal effects	activity; standard genotoxicity battery negative identified	platelet-activating factor — anticoagulant effect; not classified as reproductive toxicant at supplemental doses	flavonols undergo extensive first-pass glucuronidation; half-life 3–4 hours; renal excretion	standardised extract); EMA HMPC monograph established; not recommended during pregnancy; CRITICAL anticoagulant interaction — do not use with warfarin, aspirin, or antiplatelet drugs; ginkgolic acid <5 ppm mandatory
Ashwagandha root extract (10% withanolides) / Withania somnifera	Acute oral LD50 >2000 mg/kg bw (rat); not classified; KSM-66® and equivalent extract GRAS notifications (FDA GRN 000748)	90-day oral NOAEL 1000 mg/kg bw/day (rat); multiple human clinical RCTs at 300–600 mg/day show good tolerability	Not genotoxic; withanolides Ames test negative; no clastogenic activity; standard genotoxicity battery negative	Not recommended during pregnancy (uterotonic activity documented); ANSES precautionary warning (2024); not classified as reproductive toxicant at supplemental doses in non-pregnant adults	Withanolides absorbed in GI tract; hepatic metabolism via CYP450 enzymes; withanolide A and withaferin A documented pharmacokinetics; renal and faecal excretion	Safe at supplemental doses (300–600 mg/day); not recommended during pregnancy; caution with thyroid medication, immunosuppressants, and CNS-active drugs

Compound	Acute toxicity	Repeated-dose toxicity	Genotoxicity	Reproductive toxicity	Metabolism	Safety classification
Rhodiola Rosea extract	Acute oral LD50 >3200 mg/kg bw (rat); not classified; long traditional use in Scandinavian and Siberian phytotherapy; human studies well-tolerated at 100–680 mg/day	Subchronic oral NOAEL >100 mg/kg bw/day (rat); EMA HMPC monograph established; human studies at 100–680 mg/day demonstrate good tolerability	Not genotoxic; salidroside and rosavins Ames test negative; no clastogenic activity identified; standard genotoxicity battery negative	Not recommended during pregnancy or breastfeeding (insufficient data); EMA HMPC contraindication in pregnancy; not classified as reproductive toxicant	Salidroside and rosavins rapidly absorbed; hepatic first-pass metabolism; tyrosol (salidroside aglycone) as primary metabolite; renal excretion; half-life 4–6 hours	Safe at supplemental doses (100–680 mg/day); EMA HMPC monograph established; not recommended during pregnancy or breastfeeding; may cause agitation or insomnia at high doses; mild MAO inhibition possible — caution with antidepressants

20. FINAL LABEL TEXT

No final packaging confirmed yet. To be updated. The suitability of use and dosage of this preparation must be verified by the purchaser of the final product, in accordance with the applicable legislation in the relevant geographical territory. The manufacturer accepts no responsibility for the final labelling on product labels. Any labelling provided by the manufacturer is for guidance purposes only.

Manufacturers' recommendations on the labelling:

- Legislative name — "Food supplement" (the mandatory designation on EU-market supplement labels)
- This preparation is not intended to be used as a substitute for a varied diet. Keep out of reach of children. Store in a dry place at a temperature not exceeding 25°C, protected from direct sunlight and frost. The manufacturer accepts no liability for damage resulting from improper use or storage.
- Recommended dosage, including the statement: "Do not exceed…"
- Pack contents including weight
- Information indicating where the minimum durability date is stated (it is recommended to state — "on the packaging")
- Composition including the quantities of the main ingredients — quantities of ingredients to be stated per serving according to the dosage
- Seller — address including the country

21. DECLARATION OF COMPLIANCE

This product complies with applicable European Union legislation governing food supplements, food safety, labeling, and consumer protection.