TECHNICAL DATA SHEET & PRODUCT DOSSIER

ASHWAGANDHA CAPSULES

1. DOCUMENT CONTROL

Document title	AshwagandhaCapsules_Technical Data Sheet
Product name	Ashwagandha Capsules
Document number	FSC-TDS-008
Version	00
Prepared by	Rimante Jaseviciute
Signature	
Approved by	Sam Mallach
Signature	
Date of signing	2026 06 23

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	Ashwagandha 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	Mushroom (Ashwagandha) food supplement intended for oral use.

Target Population	Adults
Route of administration	Oral
Recommended daily intake	2 capsules

4. FORMULA COMPOSITION

Ashwagandha (Withania somnifera) – fruiting body extract in HPMC vegan capsules.

Ingredient	Amount in one capsule	Amount in recommended dose	% NRV*
Ashwagandha (Withania somnifera)	0.5 g	1.0 g	-**

* % NRV - Nutrient Reference Value (EU).

** NRV not established.

5. ACTIVE INGREDIENT SPECIFICATIONS

Ingredient Name	Ashwagandha (Withania somnifera)
CAS number	90147-43-6
EC number	290-434-9
Origin	Dried Fruiting Body
Technical data	Polysaccharides > 40 %

6. EXCIPIENTS & CAPSULE SHELL

Vegetable capsule (hydroxypropyl methylcellulose).

7. PHYSICOCHEMICAL CHARACTERISTICS

Appearance	Capsule size “0”
Colour	Transparent
Odour	No specific odour
Weight	Capsule weight: 500 mg excluding capsule (possible deviation ± 10%)
Net weight	34.8 g
Packaging	PET container
Quantity in jar	60 capsules

8. MICROBIOLOGICAL SPECIFICATION

Parameter	Limit	Result
TAMC	≤ 1 000 CFU/g	Conforms
TYMC	≤ 100 CFU/g	Conforms
Salmonella sp.	Negative/25 g	Conforms
E. coli	Negative/1 g	Conforms

9. CONTAMINANT LIMITS

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

10.DIRECTIONS FOR USE

Recommended dosage: 1–2 capsules per day – 1 in the morning / 1 in the evening. Take after a meal and wash down with a sufficient amount of water. 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	
Material	
Pack size	PET container
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. 2023/915, 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
Ashwagandha root extract / Withania somnifera (root, 10% withanolides)	Acute oral LD50 >2000 mg/kg bw (rat); not classified; KSM-66 and equivalent root extracts GRAS notification (FDA GRN 000748); multiple human RCTs at 300–600 mg/day show good tolerability	90-day oral NOAEL 1000 mg/kg bw/day (rat); multiple human clinical RCTs confirm safety at supplemental doses; no serious adverse effects at 300–600 mg/day in 8–12 week studies; ANSES issued precautionary warning in 2024 regarding hepatotoxicity and thyroid effects with long-term use	Not genotoxic; withanolides Ames test negative; no clastogenic activity; standard genotoxicity battery negative; withaferin A tested negative in bacterial mutagenicity assays	Not recommended during pregnancy — uterotonic activity documented in animal studies; ANSES precautionary warning (2024); not classified as reproductive toxicant at supplemental doses in non-pregnant adults; spermatogenic effects studied — no adverse effects at supplemental doses in male fertility studies	Withanolides absorbed in GI tract; hepatic metabolism via CYP450 enzymes (CYP3A4 and CYP2C9 involvement); withanolide A and withaferin A have documented pharmacokinetics; wide tissue distribution; renal and faecal excretion; T1/2 withanolide A approximately 6–8 hours	Safe at supplemental doses (300–600 mg/day); not recommended during pregnancy; ANSES 2024 precautionary advisory: caution with thyroid medication (may alter thyroid hormone levels), immunosuppressants, and sedative/CNS-active drugs; monitor liver function with long-term use; not recommended in patients with autoimmune conditions

20. FINAL LABEL TEXT

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.