

# TECHNICAL DATA SHEET & PRODUCT DOSSIER CHAGA CAPSULES

## 1. DOCUMENT CONTROL

|                 |                                                                                   |
|-----------------|-----------------------------------------------------------------------------------|
| Document title  | ChagaCapsules_Technical Data Sheet                                                |
| Product name    | Chaga Capsules                                                                    |
| Document number | FSC-TDS-004                                                                       |
| 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           | Chaga 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 (chaga) food supplement intended for oral use.                       |
| Target Population      | Adults                                                                        |

|                                 |            |
|---------------------------------|------------|
| <b>Route of administration</b>  | Oral       |
| <b>Recommended daily intake</b> | 2 capsules |

#### 4. FORMULA COMPOSITION

Chaga (Chaga mushroom, Inonotus obliquus) – fruiting body extract in HPMC vegan capsules.

| <b>Ingredient</b>                 | <b>Amount in one capsule</b> | <b>Amount in recommended dose</b> | <b>% NRV*</b> |
|-----------------------------------|------------------------------|-----------------------------------|---------------|
| Chaga mushroom, Inonotus obliquus | 0.5 g                        | 1.0 g                             | _**           |

\* % NRV - Nutrient Reference Value (EU).

\*\* NRV not established.

#### 5. ACTIVE INGREDIENT SPECIFICATIONS

|                        |                        |
|------------------------|------------------------|
| <b>Ingredient Name</b> | Chaga mushroom         |
| <b>CAS number</b>      | 1174002-46-0           |
| <b>EC number</b>       | Not assigned           |
| <b>Origin</b>          | Dried Fruiting Body    |
| <b>Technical data</b>  | Polysaccharides > 40 % |

#### 6. EXCIPIENTS & CAPSULE SHELL

Vegetable capsule (hydroxypropyl methylcellulose).

#### 7. PHYSICOCHEMICAL CHARACTERISTICS

|                        |                                                                         |
|------------------------|-------------------------------------------------------------------------|
| <b>Appearance</b>      | Capsule size “0”                                                        |
| <b>Colour</b>          | Transparent                                                             |
| <b>Odour</b>           | No specific odour                                                       |
| <b>Weight</b>          | Capsule weight: 500 mg excluding capsule (possible deviation $\pm$ 10%) |
| <b>Net weight</b>      | 34.8 g                                                                  |
| <b>Packaging</b>       | PET container                                                           |
| <b>Quantity in jar</b> | 60 capsules                                                             |

#### 8. MICROBIOLOGICAL SPECIFICATION

| <b>Parameter</b> | <b>Limit</b>       | <b>Result</b> |
|------------------|--------------------|---------------|
| TAMC             | $\leq$ 1 000 CFU/g | Conforms      |
| TYMC             | $\leq$ 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            |                                           |          |                           |
| - Lead                  | 3                                         | Conforms | 2023/915                  |
| - 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: 2 capsules per day. Take for 5 days per week with 2 days break, or for 3 weeks with 1 week break. Recommended to take 20 minutes before a meal. 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                  |               |
| Net quantity               | PET container |
| Primary packaging supplier |               |

## 15. MANUFACTURING DATA

Manufacturer AST Commerce & Co. s.r.o.

|                        |                        |
|------------------------|------------------------|
| <b>Certifications</b>  | Available upon request |
| <b>GMP status</b>      | No                     |
| <b>HACCP</b>           | Yes                    |
| <b>ISO certificate</b> | ISO 22716              |

## 16. REGULATORY STATUS

|                                           |                                                                                                                                                                                                                                                                                                                                                       |
|-------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Physical and chemical requirements</b> | The product complies with the requirements of Commission Regulation (EC) No. 2023/915, which sets maximum levels for certain contaminants in foodstuffs.                                                                                                                                                                                              |
| <b>Allergens</b>                          | 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. |
| <b>GMO</b>                                | 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.                                                                                                                                                                                 |
| <b>Ionization</b>                         | 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

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

## 18. QUALITY CONTROL RELEASE

| Test                                            | Specification                 | Method                                                             |
|-------------------------------------------------|-------------------------------|--------------------------------------------------------------------|
| <b>Identity (appearance)</b>                    | Conforms to description       | Visual                                                             |
| <b>Assay</b>                                    | 90-110 % of label claim       | HPLC or GC                                                         |
| <b>Uniformity</b>                               | Complies with Ph. Eur. 2.9.40 | Mass variation or content uniformity                               |
| <b>Microbiological quality (Ph. Eur. 5.1.4)</b> | As described in Section 6     | Microbial enumeration tests and tests for specified microorganisms |
| <b>Heavy metals, pesticides, mycotoxins</b>     | As described in Section 7     | ICP, HPLC, GC                                                      |
| <b>Residual solvents</b>                        | 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                                                                                                                                                                                                                  |
|-------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Chaga mushroom extract / <i>Inonotus obliquus</i> (fruiting body) | Acute oral LD50 >2000 mg/kg bw (rat); not classified; long traditional use in Russian and Nordic folk medicine; fruiting body extract well-tolerated in human studies at 400–1600 mg/day | Subchronic oral NOAEL >500 mg/kg bw/day (rat); no adverse effects at supplemental doses; 90-day human studies at 400–800 mg/day show good tolerability; no hepatotoxicity signals | Not genotoxic; Chaga polysaccharide and triterpenoid fractions Ames test negative; no clastogenic activity identified; betulin and inotodiol tested negative in standard mutagenicity assays | Not classified as reproductive toxicant; limited dedicated reproductive toxicity data available; precautionary recommendation: avoid during pregnancy (insufficient safety data); no reproductive effects identified at supplemental doses in available literature | Polysaccharides (beta-glucans) largely unabsorbed; partially degraded by gut microbiota to short-chain fatty acids; triterpenes (betulinic acid, inotodiol) absorbed and undergo hepatic glucuronidation; betulinic acid excreted biliary and renally; melanin pigments partially absorbed and excreted renally | Safe at supplemental doses (400–1600 mg/day fruiting body extract); no EFSA UL established; not recommended during pregnancy (insufficient data); caution with anticoagulant drugs (beta-glucans may potentiate antiplatelet activity) |

## 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.