TECHNICAL DATA SHEET & PRODUCT DOSSIER

HAIR COMPLEX CAPSULES

1. DOCUMENT CONTROL

Document title	HairComplex_Technical Data Sheet
Product name	HairComplex Capsules
Document number	FSC-TDS-001
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	Hair Complex 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 healthy hair growth.

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

4. FORMULA COMPOSITION

Fish skin collagen enriched with L-cystine (NATICOL® CYSKIN), enzymatic rice hydrolysate PROTHY™ R80, MSM (methylsulfonylmethane), acerola extract (containing vitamin C), stinging nettle leaf extract (Urtica dioica), vegetable capsule (hydroxypropyl methylcellulose), selenium (selenium-enriched yeast), zinc (zinc bisglycinate), anti-caking agent: magnesium stearate, silicon dioxide; copper (copper gluconate), black pepper extract BIOPERINE®, vitamin B7 (D-biotin).

Ingredient	Amount in one capsule	Amount in recommended dose	% NRV*
NATICOL® CYSKIN	150 mg	300 mg	-**
PROTHY™ R80	100 mg	200 mg	-**
MSM	100 mg	200 mg	-**
Vitamin C	20 mg	40 mg	50 %
Stinging nettle leaf extract (4 % polyphenols)	75 mg	150 mg	-**
Selenium	55 µg	110 µg	200 %
Zinc	5 mg	10 mg	100 %
Copper	0.5 mg	1 mg	100 %
BIOPERINE® (95 % piperine)	1 mg	2 mg	-**
D-biotin	50 µg	100 µg	100 %

* % NRV - Nutrient Reference Value (EU).

** NRV not established.

5. ACTIVE INGREDIENT SPECIFICATIONS

Ingredient Name	NATICOL® CYSKIN
CAS number	Collagen: 92113-31-0 / L-Cystine: 56-89-3
EC number	L-Cystine EC: 200-296-3
Origin	Enzymatic hydrolysate of EU-approved fish skin (*Gadus morhua*) combined with purified L-cystine from natural keratin.
Technical data	White powder; neutral taste and odour; >99% protein on dry basis
Ingredient Name	PROTHY™ R80
CAS number	156715-40-1
EC number	Not assigned
Origin	Partially hydrolysed rice protein by enzymatic hydrolysis
Technical data	White to off-white powder; fully water-soluble; neutral flavour
Ingredient Name	MSM
CAS number	67-71-0
EC number	200-665-9
Origin	Synthetic — produced by oxidation of DMSO
Technical data	White crystalline powder; odourless; freely soluble in water

Ingredient Name	Acerola extract
CAS number	90131-39-8
EC number	Not assigned
Origin	Botanical — fruit of *Malpighia emarginata* (West Indian cherry)
Technical data	Light orange to beige powder
Ingredient Name	Stinging nettle leaf extract (Urtica dioica)
CAS number	84012-40-8
EC number	281-676-6
Origin	Botanical — dried leaves of *Urtica dioica* L. (Urticaceae)
Technical data	Green to dark green powder
Ingredient Name	Selenium-enriched yeast
CAS number	93296-19-6
EC number	Not assigned
Origin	Biological — *Saccharomyces cerevisiae* cultivated in selenium-enriched medium
Technical data	Off-white to beige powder
Ingredient Name	Zinc bisglycinate
CAS number	14281-83-5
EC number	238-148-9
Origin	Synthetic — zinc chelated with two glycine molecules
Technical data	White to off-white powder; freely soluble in water
Ingredient Name	Copper gluconate
CAS number	527-09-3
EC number	208-408-2
Origin	Synthetic — copper salt of gluconic acid; produced by reaction of copper carbonate or copper oxide with gluconic acid
Technical data	Light blue to turquoise crystalline powder; freely soluble in water
Ingredient Name	Black pepper extract BIOPERINE
CAS number	Piperine: 94-62-2
EC number	202-350-5
Origin	Botanical — extracted from fruits of *Piper nigrum* L. and *Piper longum* L.
Technical data	Light tan to yellow powder; characteristic piperine odour
Ingredient Name	D-biotin
CAS number	58-85-5
EC number	200-399-3
Origin	Synthetic
Technical data	White crystalline powder; sparingly soluble in water; freely soluble in dilute alkali

6. EXCIPIENTS & CAPSULE SHELL

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

7. PHYSICOCHEMICAL CHARACTERISTICS

Appearance	Size “00” capsules
Colour	Transparent
Odour	No specific odour
Weight	Capsule weight: 729 mg including capsule (possible deviation ± 10%)
Packaging	150 ml brown glass jar with a 45 mm glossy black lid
Quantity in jar	60 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 2 capsules 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	No final packaging confirmed yet. To be updated.
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, 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
Hydrolyzed Fish Collagen (and) Cystine / NATICOL® CYSKIN	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; no clastogenic activity identified	Not classified; no reproductive or developmental effects at dietary doses; NOAEL >2000 mg/kg bw/day (rat)	Hydrolysed to constituent amino acids in GI tract; L-cystine metabolised via transsulphuration pathway	Safe for use in food supplements at intended doses; no safety concern identified
Hydrolyzed Rice Protein / PROTHY™ R80	Acute oral LD50 >5000 mg/kg bw (rat); not classified; GRAS status	Subchronic studies show no adverse effects at dietary levels; hypoallergenic by design	Not genotoxic; no mutagenic potential identified for hydrolysed rice protein	Not classified; no reproductive or developmental toxicity identified	Hydrolysed to constituent amino acids and small peptides in GI tract; standard amino acid metabolic pathways	Safe for use in food supplements; hypoallergenic; no safety concern identified
Methylsulfonylmethane (MSM)	Acute oral LD50 >5000 mg/kg bw (rat, OECD TG 401); not acutely toxic	90-day oral NOAEL 1500 mg/kg bw/day (rat); no adverse effects at supplemental doses	Ames test negative; chromosomal aberration test negative; not genotoxic	Not classified; no reproductive or developmental toxicity at dietary doses; NOAEL >1500 mg/kg bw/day	Metabolised to DMSO and inorganic sulphate; organic sulphur incorporated into sulphur-containing amino acids	Safe for use in food supplements; well-tolerated up to 4 g/day in humans; no safety concern identified
Acerola extract (Vitamin C)	Acute oral LD50 >5000 mg/kg bw (rat); ascorbic	No adverse effects at supplemental doses; NOAEL	Not genotoxic; Ames test negative; no	Not classified; no reproductive or developmental toxicity; NOAEL	Ascorbic acid readily absorbed; excess excreted renally as oxalate;	Safe; EFSA established UL 1000 mg/day for ascorbic acid in

Compound	Acute toxicity	Repeated-dose toxicity	Genotoxicity	Reproductive toxicity	Metabolism	Safety classification
	acid LD50 11.9 g/kg (rat)	>1000 mg/kg bw/day (rat, ascorbic acid)	clastogenic activity	>1000 mg/kg bw/day (rat, OECD TG 422)	bioflavonoids metabolised in GI tract	adults; no safety concern at supplemental doses
Urtica Dioica Leaf Extract / Stinging nettle leaf extract	Acute oral LD50 >2000 mg/kg bw (rat)	Subchronic oral NOAEL >500 mg/kg bw/day (rat); no adverse hepatic or renal effects	Not genotoxic; Ames test negative; no clastogenic activity identified	EMA HMPC: no specific reproductive concern at supplemental doses; not classified as reproductive toxicant	Flavonoids and phenolic acids metabolised hepatically; quercetin and rutin undergo conjugation and renal excretion	Safe; EMA HMPC community herbal monograph established; not recommended during pregnancy
Selenium (selenium-enriched yeast)	Acute oral LD50 for L-selenomethionine: 4.25 mg Se/kg bw (rat); organic selenium yeast lower acute toxicity than inorganic forms; Acute Tox. 3 (H301) for inorganic selenium	Subchronic oral NOAEL 0.5 mg Se/kg bw/day (rat, 90-day); EFSA UL 300 µg/day for adults	Not genotoxic at nutritional doses; high-dose selenium pro-oxidant; Ames test negative	Not classified as reproductive toxicant at nutritional doses; high doses associated with reproductive effects in animals; EFSA UL applies	Incorporated into selenoproteins (glutathione peroxidase, thioredoxin reductase); excess excreted as urinary selenite and trimethylselenonium	Safe at intended supplement doses (≤200 µg/day); EFSA UL 300 µg/day must not be exceeded
Zinc bisglycinate	Acute oral LD50 for zinc compounds: 350–	Subchronic oral NOAEL 30 mg Zn/kg bw/day	Not genotoxic; zinc ion Ames test negative; no	Not classified as reproductive toxicant at nutritional doses;	Absorbed as zinc glycinate chelate; released zinc ion utilised as	Safe at intended supplement doses; EFSA UL 25 mg zinc/day

Compound	Acute toxicity	Repeated-dose toxicity	Genotoxicity	Reproductive toxicity	Metabolism	Safety classification
	600 mg/kg bw (rat) as zinc ion	(rat); EFSA UL 25 mg/day for adults	clastogenic activity	essential micronutrient; excess also harmful at very high doses	cofactor in >300 enzymes; excess excreted faecally	for adults; bisglycinate form superior bioavailability and gastric tolerability
Copper Gluconate	Acute oral LD50 ~794 mg Cu/kg bw (rat) as copper ion; CLP: Acute Tox. 4 oral (H302); Aquatic Chronic 1 (H410)	Subchronic oral NOAEL 0.5 mg Cu/kg bw/day (rat); EFSA UL 5 mg/day for adults	Not genotoxic at nutritional doses; excess copper pro-oxidant; Ames test negative	Not classified as reproductive toxicant at nutritional doses; copper essential for foetal development; Wilson's disease population at risk	Absorbed in small intestine; transported bound to albumin and ceruloplasmin; excess excreted biliary	Safe at intended supplement doses; EFSA UL 5 mg copper/day for adults; gluconate form well-tolerated and highly bioavailable
Piper Nigrum Fruit Extract / BIOPERINE® (95% piperine)	Acute oral LD50 514 mg/kg bw (rat); not classified at supplemental doses of 5–10 mg/day	Subchronic oral NOAEL 100 mg/kg bw/day (rat, 90-day); no adverse effects at supplemental doses	Ames test equivocal at high doses in some bacterial studies; negative in mammalian cell assays; not classified as mutagen at supplemental doses	Not classified; piperine enhances placental permeability at high doses in animals; not recommended during pregnancy at high doses	Rapidly absorbed; metabolised by CYP3A4 and UGT; inhibits P-glycoprotein and CYP3A4 — drug interaction potential; half-life ~6–8 hours	Safe at 5–10 mg/day; drug interaction caution — increases bioavailability of co-administered pharmaceuticals; not recommended in pregnancy
D-Biotin (Vitamin B7)	Acute oral LD50 >2000 mg/kg bw (rat); not acutely toxic; not classified	Subchronic oral NOAEL >2000 mg/kg bw/day (rat); no adverse effects identified	Not genotoxic; Ames test negative; no clastogenic activity	Not classified; essential vitamin for foetal development; no adverse	Water-soluble vitamin; absorbed via sodium-dependent multivitamin	Safe; no EFSA UL established; high-dose biotin (≥5 mg) may interfere with

Compound	Acute toxicity	Repeated-dose toxicity	Genotoxicity	Reproductive toxicity	Metabolism	Safety classification
		even at very high doses		reproductive effects at supplemental doses	transporter (SMVT); excess excreted renally unchanged; no accumulation	immunoassay-based laboratory tests

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.