

TECHNICAL DATA SHEET

ORGANIC GINKGO BILOBA LE DE PR2874

Organic labelling regulation
(UE) 2018/848 - art.32):

BIO = DE-ÖKO-039

Botanical kind:

Organic Ginkgoaceae Ginkgo biloba L.

Part of the plant:

Leaf

Extraction solvent(s):

Ethanol, water 30 : 70 (V/V)

Carrier(s):

Organic maltodextrin

DESCRIPTION

| | Specifications | Methods and references |
|------------|---|------------------------|
| Appearance | <i>Powder</i> | |
| Color | <i>Beige to light brown</i> | |
| Odor | <i>Characteristic</i> | |
| Taste | <i>Very bitter</i> | |
| Solubility | <i>To be tested following the degree of incorporation</i> | |

ANALYSES

| | Specifications | | Method and reference |
|--|------------------|--------|---|
| | Min | Max | |
| Flavonoids, expressed as flavone glycosides content [%] | - | < 2.00 | AE-40 - HPLC, Eur. Ph. (04/2008:1827), "Ginkgo dry extract, refined and quantified" monograph |
| Terpene lactones content [%] | - | < 0.50 | AE-40 - HPLC, Eur. Ph. (04/2008:1827), "Ginkgo dry extract, refined and quantified" monograph |
| Ginkgolic acid content expressed as ginkgolic acid C17 [ppm] | Indicative value | | AE-40 - HPLC, Eur. Ph. (04/2008:1827), "Ginkgo dry extract, refined and quantified" monograph |
| Identification (raw material) (4) | Complies | | MO-85 - TLC, Eur. Ph. (01/2011:1828), "Ginkgo leaf" monograph |
| Loss on drying [%] | - | 5.00 | MO-183 - Eur. Ph. (01/2008:20817) and (02/2008:20816) |
| Bulk density | 0.30 | 0.70 | MO-181 - Eur. Ph. (04/2019:20934) |
| pH (1% in demineralized water) | 3.0 | 6.5 | MO-03 - pH-meter, Eur. Ph. (07/2016:20203), "Potentiometric determination of pH" monograph |
| Screening [% < 500 µm] | 95.0 | - | MO-184 - Granulometer, internal method |

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| CONTAMINANTS | Specifications | | Method and reference |
|---|-------------------|--------|--|
| | Min | Max | |
| Pb content [ppm] (4) | - | < 3.00 | AE-01 - ICP, internal method test |
| Cd content [ppm] (4) | - | < 1.00 | AE-01 - ICP, internal method test |
| Hg content [ppm] (4) | - | < 0.10 | AE-01 - ICP, internal method test |
| As content [ppm] (4) | - | < 1.00 | AE-01 - ICP, internal method test |
| Pesticides content [ppm] (4) | < detection limit | | AE-02 - GC-MSMS/LC-MSMS, internal method |
| PaHs (sum of benzo(a) pyrene, benz(a) anthracene, benzo(b) fluoranthene and chrysene) content [ppb] (4) | - | < 50.0 | AE-03 - GC-MS-MS, internal method |
| Benzo(a)pyrene content [ppb] (4) | - | < 10.0 | AE-03 - GC-MS-MS, internal method |

| MICROBIOLOGY | Specifications | | Method and reference |
|--|----------------|----------|--|
| | Min | Max | |
| Total aerobic microbial count [CFU/g] (1) | - | < 10 000 | AE-04 - Eur. Ph. (07/2010:20612) and (01/2014:20631) |
| Total yeasts/moulds count [CFU/g] (1) | - | < 100 | AE-04 - Eur. Ph. (07/2010:20612) and (01/2014:20631) |
| Salmonella content [/25g] | Absent | | AE-04 - Eur. Ph. (07/2010:20612) and (01/2014:20631) |
| Bile-tolerant Gram negative bacteria content [CFU/g] | - | < 100 | AE-04 - Eur. Ph. (07/2010:20612) and (01/2014:20631) |
| Escherichia coli content [/g] | Absent | | AE-04 - Eur. Ph. (07/2010:20612) and (01/2014:20631) |

(1) Acceptable maximal count: 5 times the acceptance criterion according to Eur. Ph. VIII° Ed. 5.1.8 Category B

(4) HACCP based control plan defined annually according to risk analysis

Best before/ 24

DMD (in months) :

Storage conditions: Store in closed original packaging at 5 to 25°C in a dry place and protected from light.

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INFORMATION ABOVE AS RECEIVED FROM OUR SUPPLIER

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**Complementary
data**

*This reference is neither an Active Pharmaceutical Ingredient nor an excipient for pharmaceutical use
Responsibility of final labelling lies with the company placing the final product on the market.*

- *Complies with French decrees (2006-352 and 24th June 2014)*
- *According to Regulation 1999/3/EC, and its modifications, has not been ionized.*
- *According to the Regulations 2001/18/EC, 1829/2003 and 1830/2003, and its modifications, the above mentioned item does not contain deliberately added GMO. (fortuitous or technically inevitable traces could be detected at less than 0,9%)*
- *The product does not contain TSE/BSE substances*