

TECHNICAL DATA SHEET

GINGER RH 1:1 DE PR7288

| | |
|-------------------------------------|--|
| Botanical kind: | Zingiberaceae Zingiber officinale Roscoe |
| Part of the plant: | Rhizome |
| Ratio plant / final extract: | 1 to 1 (a) |
| Extraction solvent(s): | Water |
| Carrier(s): | Wheat maltodextrin |

DESCRIPTION

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

ANALYSES

| | Specifications | | Method and reference |
|--|-------------------------|------|---|
| | Min | Max | |
| Methyleugenol content [ppm] (4) | <i>Indicative value</i> | | <i>AE-22 - GC-MS, internal method for aromatic substances</i> |
| Identification (raw material) (4) | <i>Complies</i> | | <i>MO-84 - TLC, Eur. Ph. (01/2011:1522), "Ginger" monograph</i> |
| Loss on drying [%] (11) | - | 8.00 | <i>MO-183 - Eur. Ph. (01/2008:20817) and (02/2008:20816)</i> |
| Bulk density | 0.30 | 0.70 | <i>MO-181 - Eur. Ph. (04/2019:20934)</i> |
| pH (1% in demineralized water) (11) | 4.0 | 9.0 | <i>MO-03 - pH-meter, Eur. Ph. (07/2016:20203), "Potentiometric determination of pH" monograph</i> |
| Screening [% < 500 µm] | 95.0 | - | <i>MO-184 - Granulometer, internal method</i> |

CONTAMINANTS

| | Specifications | | Method and reference |
|-----------------------------|----------------|--------|-------------------------------------|
| | Min | Max | |
| Pb content [ppm] (4) | - | < 3.00 | <i>AE-01 - ICP, internal method</i> |
| Cd content [ppm] (4) | - | < 1.00 | <i>AE-01 - ICP, internal method</i> |
| Hg content [ppm] (4) | - | < 0.10 | <i>AE-01 - ICP, internal method</i> |
| As content [ppm] (4) | - | < 1.00 | <i>AE-01 - ICP, internal method</i> |

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|--|--|--------|--|
| Pesticides content [ppm] (4) | < Residual Maximum Limit fixed in European regulation 396/2005 and its modifications | | AE-02 - GC-MSMS/LC-MSMS, internal method |
| Benzo(a)pyrene content [ppb] (4) | - | < 10.0 | AE-03 - GC-MS-MS, internal method |
| PAHs (sum of benzo(a)pyrene, benzo(a)anthracene, benzo(b)fluoranthene and chrysene) content [ppb] (4) | - | < 50.0 | AE-03 - GC-MS-MS, internal method |

| MICROBIOLOGY | Specifications | | Method and reference |
|--|----------------|----------|-------------------------------------|
| | Min | Max | |
| Total aerobic microbial count [CFU/g] (1) | - | < 10 000 | MO-191 - Pétrifilm TM / ISO 4833 |
| Total yeasts/moulds count [CFU/g] (1) | - | < 100 | MO-192 - Pétrifilm TM / AOAC 997.02 |
| Salmonella content [/25g] | Absent | | MO-193 - TECRA TM / ISO 6579 |
| Enterobacteria content [CFU/g] | - | < 100 | MO-194 - Pétrifilm TM ISO 21528-2 |
| Escherichia coli content [CFU/g] | - | < 10 | MO-195 - Pétrifilm TM / ISO 16649-2 |

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

(11) First ten batches

(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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Complementary data

(a): Variable indicative raw material ratio depending on productions and / or variability of the raw material.
Non contractual 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*