

TECHNICAL DATA SHEET

ORGANIC YELLOW GENTIAN RO 3:1 DE PR2144

Organic labelling regulation
(UE) 2018/848 - art.32): BIO = DE-ÖKO-039

Botanical kind: Gentianaceae Gentiana lutea L.
Part of the plant: Root
Ratio plant / final extract: 3 to 1 (a)
Extraction solvent(s): Water
Carrier(s): Organic 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	
Loss on drying [%] (11)	-	8.00	MO-183 - <i>Eur. Ph. (01/2008:20817) and (02/2008:20816)</i>
Bulk density	0.30	0.70	MO-181 - <i>Eur. Ph. (04/2019:20934)</i>
pH (1% in demineralized water) (11)	3.0	6.5	MO-03 - <i>pH-meter, Eur. Ph. (07/2016:20203), "Potentiometric determination of pH" monograph</i>
Screening [% < 500 µm]	95.0	-	MO-184 - <i>Granulometer, internal method</i>

CONTAMINANTS

	Specifications		Method and reference
	Min	Max	
Pb content [ppm] (2)	-	< 3.00	AE-01 - <i>ICP, internal method</i>
Cd content [ppm] (2)	-	< 1.00	AE-01 - <i>ICP, internal method</i>
Hg content [ppm] (2)	-	< 0.10	AE-01 - <i>ICP, internal method</i>
Pesticides content [ppm] (2)	< detection limit		AE-02 - <i>GC-MSMS/LC-MSMS, internal method</i>
Benzo(a)pyrene content [ppb] (2)	-	< 10.0	AE-03 - <i>GC-MS-MS, internal method</i>

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Pahs (sum of benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene) content [ppb] (2)	-	< 50.0	AE-03 - GC-MS-MS, internal method
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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

(2) On request with additional cost

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.

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.
- 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*