

## TECHNICAL DATA SHEET

### ORGANIC YELLOW GENTIAN RO 3:1 DE PR2144

<b>Organic labelling regulation</b> ((UE) 2018/848 - art.32):	BIO = DE-ÖKO-039
<b>Botanical kind:</b>	Gentianaceae Gentiana lutea L.
<b>Part of the plant:</b>	Root
<b>Ratio plant / final extract:</b>	3 to 1 (a)
<b>Extraction solvent(s):</b>	Water
<b>Carrier(s):</b>	Organic wheat maltodextrin

#### DESCRIPTION

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

#### ANALYSES

	Specifications		Method and reference
	Min	Max	
<b>Loss on drying [%] (11)</b>	-	8.00	MO-183 - Eur. Ph. (01/2008:20817) and (02/2008:20816)
<b>Bulk density</b>	0.30	0.70	MO-181 - Eur. Ph. (04/2019:20934)
<b>pH (1% in demineralized water) (11)</b>	3.0	6.5	MO-03 - pH-meter, Eur. Ph. (07/2016:20203), "Potentiometric determination of pH" monograph
<b>Screening [% &lt; 500 µm]</b>	95.0	-	MO-184 - Granulometer, internal method

#### CONTAMINANTS

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

## TECHNICAL DATA SHEET

### ORGANIC YELLOW GENTIAN RO 3:1 DE PR2144

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

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