

TECHNICAL DATA SHEET

ORGANIC GERMAN CHAMOMILE FL 4:1 DE PR2585

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

BIO = DE-ÖKO-039

Botanical kind:

Organic Compositae Matricaria recutita L. (= Matricaria chamomilla L.)

Part of the plant:

Flower

Ratio plant / final extract:

4 to 1 (a)

Extraction solvent(s):

Water

Carrier(s):

Organic wheat maltodextrin

DESCRIPTION

	Specifications	Methods and references
Appearance	Hygroscopic powder	
Color	Beige to brown	
Solubility	To be tested following the degree of incorporation	

ANALYSES

	Specifications		Method and reference
	Min	Max	
Alpha-bisabolol content [ppm] (2)	Indicative value		AE-42 - GC-MS, internal method
Total apigenin 7-glucoside content [%] (2)	Indicative value		MO-49 - HPLC, Eur. Ph. (01/2016:0404), "Matricaria flower" monograph
Loss on drying [%] (11)	-	8.00	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) (11)	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

CONTAMINANTS

	Specifications		Method and reference
	Min	Max	
Pb content [ppm] (2)	-	0.50	AE-01 - ICP, internal method
Cd content [ppm] (2)	-	< 1.00	AE-01 - ICP, internal method
Hg content [ppm] (2)	-	< 0.10	AE-01 - ICP, internal method

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Pesticides content [ppm] (2)	<i>< detection limit</i>		<i>AE-02 - GC-MSMS/LC-MSMS, internal method</i>
Benzo(a)pyrene content [ppb] (2)	-	<i>< 10.0</i>	<i>AE-03 - GC-MS-MS, internal method</i>
PaHs (sum of benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene) content [ppb] (2)	-	<i>< 50.0</i>	<i>AE-03 - GC-MS-MS, internal method</i>

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

(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.

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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.
- 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*