

TECHNICAL DATA SHEET

ORGANIC MEADOWSWEET FT 5:1 DE PR426

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

BIO = DE-ÖKO-039

Botanical kind:

Organic Rosaceae Spiraea ulmaria L. (= Filipendula ulmaria (L.) Maxim.)

Part of the plant:

Flowering top

Ratio plant / final extract:

5 to 1 (a)

Extraction solvent(s):

Water

Carrier(s):

Organic 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	
Salicylic acid content [%] (2)	<i>Indicative value</i>		<i>AE-230 - HPLC, internal method</i>
Salicylaldehyde content [ppm] (2)	<i>Indicative value</i>		<i>AE-88 - HPLC, internal method</i>
Methyl salicylate content [%] (2)	<i>Indicative value</i>		<i>AE-36 - GC-MS, internal method</i>
Total flavonoids, expressed as rutin content [%] (2)	<i>Indicative value</i>		<i>MO-21 - UV-Vis, Fr. Ph. (1996), "Cassis (feuille de)" monograph</i>
Identification (raw material) (2)	<i>Complies</i>		<i>MO-75 - TLC, Eur. Ph. (04/2013:1868), "Meadowsweet" 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>
Total ash content [%] (11)	-	< 10.00	<i>MO-01 - Muffle furnace, Eur. Ph. (01/2008:20416), "Total ash" adapted monograph</i>
pH (1% in demineralized water) (11)	3.5	6.5	<i>MO-03 - pH-meter, Eur. Ph. (07/2016:20203), "Potentiometric determination of pH" monograph</i>

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Screening [% < 500 µm]	95.0	-	MO-184 - Granulometer, internal method
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CONTAMINANTS	Specifications		Method and reference
	Min	Max	
Pb content [ppm] (2)	-	< 3.00	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
As content [ppm] (2)	-	< 1.00	AE-01 - ICP, internal method
Pesticides content [ppm] (2)	< detection limit		AE-02 - GC-MSMS/LC-MSMS, internal method
Benzo(a)pyrene content [ppb] (2)	-	< 10.0	AE-03 - GC-MS-MS, internal method
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

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

(11) First ten batches

(2) On request with additional cost

Best before/ 24
DMD (in months) :

Version: 4 of Wed, 07 Feb 2024

Document created on Fri, 18 Dec 2020

INFORMATION ABOVE AS RECEIVED FROM OUR SUPPLIER

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**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